In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 15-095V
(to be published)

* *	Special Master Corcoran
GLORIA MASSEY CHINEA, *	
Petitioner, *	Filed: March 15, 2019
v. *	Decision; Influenza ("flu") Vaccine; Guillain-Barré syndrome ("GBS"); Onset
SECRETARY OF HEALTH AND HUMAN SERVICES, *	
Respondent. *	
* *	

Lisa A. Roquemore, Law Office of Lisa Roquemore, Rancho Santa Margarita, CA, for Petitioner.

Christine M. Becer, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DENYING ENTITLEMENT[1]

On October 9, 2015, Mrs. Gloria Chinea filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] Petitioner alleges that she experienced Guillain-Barré syndrome ("GBS") due to receipt of the influenza ("flu") vaccine on October 31, 2012.

An entitlement hearing was held on August 6-7, 2018. For the reasons stated in more detail below, Petitioner has not demonstrated entitlement to compensation under the Vaccine Program.

[1] This Decision has been formally designated "to be published," and will be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

The medical records in this case support the conclusion that Petitioner's GBS symptoms began in late January 2013 – well outside the six to eight-week timeframe from vaccination that Program decisions recognize as medically reasonable. Through her own testimony as well as that of several credible fact witnesses, Petitioner has established that in the fall of 2012, she was more likely than not experiencing fatigue and other symptoms that were negatively impacting her health and quality of life. But Petitioner has *not* established (via expert testimony or otherwise) that those symptoms had any relationship to her subsequently-diagnosed GBS, or that the October 2012 vaccination initiated a slow, "smoldering" form of GBS, given the extent to which her late fall symptoms were inconsistent with GBS's typically acute presentation.

I. Factual Background – Medical Record

The evidentiary record in this case consists of Mrs. Chinea's medical records, the testimony and sworn statements of multiple fact witnesses and two experts, plus the medical or scientific literature submitted by the parties in support of their respective positions. I have reviewed the entire record as required by the Vaccine Act. Before discussing fact witness testimony, I will recount what the medical record reveals in this case.

Petitioner's Pre-Vaccination Health

Mrs. Chinea was born on July 7, 1956. Before the time period in dispute, she was a generally healthy woman for her age with only minor health issues, such as high cholesterol (which was successfully treated), some hypertension, asthma and allergies, type 2 diabetes, and conductive hearing loss. Ex. 1 at 33. However, the record does establish that in the year prior to the October 2012 vaccination, she experienced a number of symptoms congruent with those at issue in this case. Thus, on May 31, 2011, Petitioner presented to her primary care physician (Dr. Sergio Neira) with complaints of blurred vision, impaired hearing, urinary incontinence, and leg pain, and continued to experience these symptoms into the late summer that year. Ex. 1 at 30, 33. Her assessment included hypertension, menopausal syndrome, and included a screening for tuberculosis. *Id.* at 31.

On May 10, 2012, Petitioner returned to Dr. Neira complaining of depression, stress, and premenstrual tension syndrome. Ex. 1 at 21. Her physical examination was normal, however, and the overall assessment was consistent with her past diagnosed health problems (i.e., hypertension and high cholesterol). *Id.* On July 25, 2012, Mrs. Chinea presented to Dr. Neira complaining of a rash (with associated burning and extreme fatigue). *Id.* at 18. She was diagnosed with shingles and placed on acyclovir and prednisone. *Id.* at 19-20. Petitioner was also treated for post-herpetic neuralgia on August 9, 2012. *Id.* at 15.

Vaccination and Immediate Aftermath

On October 31, 2012, Mrs. Chinea went back to Dr. Neira for a routine appointment. She reported some wheezing due to allergens. Ex. 1 at 11. In addition, her then-current problems were listed as conductive hearing loss, fatigue, and post-herpetic neuralgia (consistent with her prior diagnoses). *Id.* at 12. She received the flu vaccination (Fluvirin, lot #1205001) in her left deltoid as part of her general health maintenance. *Id.* at 1, 43. There is no subsequent medical record setting forth any purported reaction to this vaccination, and nothing from the month of November that would corroborate the allegations of any adverse symptoms around this time.

Nearly six weeks later, on December 10, 2012, Petitioner saw her gynecologist, Dr. Adrienne Lara, for an annual exam. Ex. 4 at 3. The record from this visit indicates that Dr. Lara's review of symptoms was normal. *Id.* at 4. In particular, she did not record any complaints by Petitioner of weakness, fatigue, or anything else that might appear a precursor of GBS as classically understood (*e.g.*, paresthesias, numbness of tingling in the limbs, difficulty walking, etc.). *See id.* Records from this visit explicitly state that Petitioner "continues to be successful and it is going to be a good year. There was nothing else on her mind." *Id.* On December 11, 2012, Petitioner had an endometrial biopsy. *Id.* at 2. Later that month, on December 21, 2012, she had a follow-up to get the results of the biopsy. *Id.* at 1. No additional complaints were noted at that time either. *Id.*

GBS Presentation

There is another, almost one-month records gap before Petitioner next saw a medical treater – but this next set of records is what best establishes Petitioner's GBS and how it presented. Thus, on January 28, 2013, Petitioner began to experience "profound[] weakness," plus other adverse symptoms (headaches, dizziness, balance issues, congestion, and voice problems) sufficient to be alarming to her and her husband, Mr. Rolando Chinea. Ex. 7 at 4; Ex. 1 at 40. At first, Petitioner simply sought treatment from Dr. Neira. Ex. 1 at 39-40. The record reveals that Petitioner's husband telephoned Dr. Neira's office on January 30, 2013, to report the above-noted symptoms and obtain a Tamiflu prescription. *Id.* at 40. But by January 31, 2013, the Chineas were concerned enough about Petitioner's health to seek urgent care intervention, and Mrs. Chinea was taken to the emergency room at Community Memorial Health System. Ex. 7 at 4.

There, Petitioner was evaluated by a neurologist, Dr. Paul Vespa, at which time her chief complaint was "generalized weakness." Ex. 7 at 4. Petitioner specifically reported that she began experiencing upper respiratory symptoms about eleven days prior (meaning no earlier than mid-January). *Id.* But before onset, Petitioner reported being in generally good health, able to complete her normal exercise classes and take hour-long walks around the neighborhood in the days prior.

Id. at 8, 10. It was also noted that Petitioner had a history of asthma/cat allergies, and that in the two weeks prior, she had been exposed to a cat (which resulted in congestion/conjunctivitis/rhinitis that "lasted for several days"). *Id.* at 6, 7-8. After this exposure, she experienced shortness of breath about one week later, then profound weakness in the two to three days prior to admission. *Id.* She stated that she had lost her voice, was unable to walk or hold her head up, and had impaired sensation in the hands and feet. *Id.* Her physical examination was significant for slurred speech, slow movements in all four limbs, absent deep tendon reflexes, and decreased muscle strength (3/5 bilateral in both upper and lower extremities). *Id.* at 5. She also had paresthesia of the hands and feet. *Id.* Lab reports indicated negative testing for the influenza A and B virus. *Id.* at 4.

Petitioner was diagnosed with acute respiratory failure with upper airway edema and diffuse neuromuscular weakness. Ex. 7 at 7-8. Her medical records indicate that she was intubated and placed on ventilator support thereafter. *Id.* Petitioner was evaluated by another neurologist, Dr. Francisco Torres, on February 1, 2013. *Id.* at 10. In his consult, Dr. Torres indicated that Petitioner was in her "usual state of health" until January 28, 2013, with congestion, imbalance, and flu-like symptoms manifesting on the 29th (and thus immediately prior to her ER presentation). *Id.* Upon exam, her deep tendon reflexes were absent. *Id.* at 11. Lower extremities were noted to have normal distal strength. *Id.* Upper extremities were described as 2/3 in the deltoids, with 3+ to 4/5 in the biceps and triceps. *Id.* Dr. Torres opined that Petitioner had GBS given her history of flu-like symptoms, although he also included myasthenia gravis and botulism in the differential diagnosis. *Id.*

Mrs. Chinea remained hospitalized for several days thereafter. She tested positive for the GQ1B antibody (which as discussed below is associated with the form of neuropathy with which Petitioner was subsequently diagnosed). Ex. 7 at 52-52, 71-72. Following this confirmation, she was treated with a five-day course of IVIG. *Id.* at 1-2. She was extubated on February 15, 2013, and was monitored thereafter for treatment success. *Id.* at 2. Her final hospital diagnosis was determined to be GBS, Miller-Fisher variant. *Id.* On February 26, 2013, Petitioner was discharged and transferred to St. John's Regional Medical Center for acute inpatient rehabilitation, where she remained for approximately one month. Ex. 7 at 2; *see also* Ex. 6 at 10. She was discharged on March 23, 2013, having made "excellent progress." Ex. 6 at 10. By this time, Petitioner was able to ambulate with the use of a walker and climb steps, although she continued to have some dysphagia and pain upon discharge. *Id.*

Identification of Flu Vaccine as Possibly Causal of Petitioner's GBS

Throughout the spring and summer of 2013, Mrs. Chinea continued to receive treatment for her GBS and the unresolved sequelae she was experiencing from it (which included ongoing paresthesias, weakness, and pain). *See, e.g.*, Ex. 1 at 7-10; Ex. 3 at 9, 11-14. Prior to this time, the

records do not include any notation in which a treater proposed that the flu vaccine Petitioner had received the prior fall had any association with her GBS symptoms beginning in January 2013.[3] However, at a June 2013 visit with Dr. Neira, Petitioner stated "MD at hospital told her she had an adverse reaction to [the] [i]nfluenza vaccine." Ex. 1 at 7. Dr. Neira and Petitioner specifically discussed at this time her seeking legal counsel concerning a reaction to the flu vaccine. *Id.* at 9. At a follow-up visit on October 17, 2013, Dr. Neira's notes indicated that Petitioner's GBS "may have been caused by [the] flu vaccine[,]" but included no additional comments concerning the onset of symptoms. *Id.* at 73. He also seemingly recommended that Petitioner not receive the flu vaccine in the future. *Id.* at 77 ("other orders: [n]o flu vaccine ever").

On June 24, 2013, Dr. Neira submitted a VAERS report on Petitioner's behalf. Ex. 2 at 1-3. Dr. Neira noted the vaccination date as October 31, 2012, and the adverse event date as January 31, 2013. *Id.* at 2. However, the report was modified on January 28, 2014, with additional information emailed to VAERS by an employee from Dr. Neira's office. Ex. 10 at 17. The new submissions indicated that Petitioner had actually experienced associated fatigue *prior* to Thanksgiving 2012 (i.e., "experienced different exhaustion than before"), as well as weakness, blurred vision, voice hoarseness, and "difficulty lifting left arm." *Id.* The VAERS report was updated a second time on July 17, 2014. Ex. 9 at 1-5. It now included an attached list of residual GBS symptoms that Dr. Neira reported were associated with Petitioner's receipt of the flu vaccine, along with a summary of the treatment and therapy she received. *Id.* at 3-4, 5. However, no correction was made to the reported symptom onset date of January 31, 2013. *See id.* at 1-5.

By September and December 2013, Petitioner's treaters felt that she had mostly recovered from her GBS. Ex. 3 at 15-17. She nevertheless continued to attend physical therapy throughout 2013 and 2014. Ex. 10 at 14.

II. Fact Witness Testimony

A. *Mrs. Gloria Chinea*

Petitioner was the first witness to testify at hearing. Tr. at 5-102. Her testimony largely consisted of her own recollection of her overall health history, pre- and post-vaccination, with some additional explanation of disputed issues relevant to certain medical records.

[3] The health history taken upon Petitioner's presentation to the hospital on January 31, 2013, indicated that she "did receive a flu shot this season." Ex. 7 at 4. However, the intake physician did not opine as to any causal connection between her symptoms and the vaccine. *See id.* Apart from this one reference, it does not appear that any other hospital treater considered the vaccine to be causative of her onset of GBS. *See generally* Ex. 7.

Mrs. Chinea began by describing her educational and employment background. She received a bachelor's degree in nutrition and dietetics, followed by a master's in public health. Tr. at 6. Following graduate school, she worked as a health education specialist at St. John's Regional Medical Center in Oxnard, California. *Id.* She retired from the hospital after twenty-one years of service and worked briefly at a home mortgage firm thereafter. *Id.* at 6-7. In 2009, Petitioner opened Alma Joy Villa, a residential care facility for the elderly, and serves as its Director of Activities. *Id.* at 7, 17.

Prior to her receipt of the flu vaccine, Petitioner testified that she was in "excellent" health. Tr. at 16. She attended church each morning and typically arrived to work around 7:00 AM. *Id.* at 16-17. Petitioner stated that her days at Alma Joy Villa were busy, given that she was involved in all aspects of patient care (including cognitive exercises, physical care, and attending meetings with caretakers and physicians). *Id.* at 17. She also routinely participated in outdoor activities (including walks with her dog and going to the gym) and was able to complete various household tasks such as grocery shopping and cooking meals. *Id.* at 18. She felt like the "energizer bunny rabbit." *Id.* at 19. Petitioner specifically denied experiencing any significantly adverse health problems or extreme fatigue prior to receiving her vaccination (despite the record evidence set forth above recording some symptoms that echo those alleged to have been experienced in the fall of 2012). *Id.* at 63-64.[4]

Following receipt of the flu vaccine on October 31, 2012, Petitioner maintains that she began to notice a "lack of energy" roughly "a week or two" following vaccine administration (or between the first and second week of November 2012). Tr. at 19, 52, 80. In particular, she recalled feeling fatigued and sleepy (i.e., taking naps) which was unusual for her. *Id.* at 19, 80. She also reported "feel[ing] low" and having pain in her vaccinated arm. *Id.* at 20 (arm "feels warm"), 21, 81-83.[5] She testified that the arm pain lasted until her January 2013 hospitalization and was accompanied by a raised bump (or "mark" on the arm) and redness. *Id.* at 82-83. Apart from the above, Petitioner denied experiencing any other problems at this time (for example, cold symptoms). *Id.* at 21. In support of the above, Petitioner referenced phone records (Ex. 74) from one of her patient's relatives (Dr. Diane Moore, who also testified at hearing). *Id.* at 21-23. According to Petitioner, such records reveal that she was a "no-show" to a meeting scheduled to

[4] On cross examination Respondent pointed to a record dated July 25, 2012, which indicated that Mrs. Chinea had presented to a nurse practitioner at Dr. Neira's office with possible shingles and had specifically reported "still" feeling "extremely fatigued" at that time. Tr. at 85-84 (citing Ex. 1 at 18). Petitioner, however, maintained that this record was an inaccurate description of how she was actually feeling that day. *Id.* at 86 ("I did not tell her that I had what you read me, extremely fatigued"). Petitioner otherwise stated the fatigue she felt in July 2012 was distinguishable from what she felt following her receipt of the vaccine. *Id.* at 85.

[5] At hearing, Petitioner recalled a meeting with her Bible study group when she asked for prayer to restore her formerly high energy level. Tr. at 20.

take place with Dr. Moore on November 14, 2012, because she overslept. *Id.* at 23. Following the missed meeting, Petitioner reported she continued to feel tired and experience hoarseness. *Id.* at 24. She could not, however, reference medical records corroborating these allegations.

Mrs. Chinea next testified about the progression of her symptoms over the 2012 Thanksgiving holiday. Petitioner described her typical Thanksgiving as a big family event filled with cooking and preparing meals for the homebound, as well as assisting with celebrations at Alma Joy Villa. Tr. at 24-25. However, that year she "didn't have much energy," felt tired and achy, and was unable to participate in the above-mentioned activities.[6] *Id.* at 26, 100-02. She was also purportedly experiencing at this time heightened sensitivity to touch, a sensation of an "overgrown" tongue, and "taste of metal" in her mouth. *Id.* at 26-27, 100. And she began to have trouble swallowing, now preferring a bland diet filled with liquids or soft foods. *Id.* at 27-28.[7] In addition, she started experiencing leg jerks at night, plus blurred vision when looking at a computer screen, along with a lack of hand strength when attempting to open bottles or coffee containers, and felt "intermittent" tingling in her hands and toes. *Id.* at 28-29, 100.

Because she did not feel up to hosting her own Thanksgiving celebration, Petitioner attended Thanksgiving 2012 at the home of a family friend, Dr. Arturo Sidransky. Tr. at 30. Other friends were in attendance as well, including Ms. Enjoli Flores. *Id.* Petitioner did not have much appetite and recalled that she was "quiet" and felt "tired" throughout the evening. *Id.* at 31. Petitioner also stated that she was unable to participate in post-Thanksgiving "Black Friday" shopping that year due to her fatigue/tiredness (an activity that she usually looked forward to). *Id.* at 32-33.

Petitioner provided some detailed testimony regarding her aforementioned visit to her OB/GYN, Dr. Lara, in December 2012. Tr. at 33-34. In addition to the need for routine testing, Petitioner testified that she was experiencing adverse gynecological symptoms (including vaginal discharge and bleeding) which prompted the visit. *Id.* at 34. Contrary to the original medical records from this visit, however (which make no mention of any non-gynecologic symptoms, and even suggest that Petitioner was in her usual health overall), Petitioner testified that she also discussed her feelings of tiredness and lack of energy[8] with Dr. Lara (along with a concern for an

[6] Petitioner also stated her tiredness caused her to be less active (i.e. she could not complete her routine exercise classes at the 24-Hour Fitness gym). Tr. at 81.

[7] At the same time, however (and somewhat contradictorily to the foregoing), she also began to eat spicy food which was unusual for her. Tr. at 28 ("I noticed I was eating more Cholula [a hot sauce].").

[8] On cross, Petitioner stated that she was acquainted with Dr. Lara through her professional activities prior to December 2012. Tr. at 70-72. Thus, in her view, Dr. Lara would have been well aware of her typical energy level.

iron deficiency, sleepiness, loss of appetite, swollen mouth, and issues with body temperature). *Id.* at 34, 38, 96-97.

To support her contentions that she did in fact inform Dr. Lara of the non-gynecologic symptoms she was experiencing at that time, Petitioner maintained that she had prepared notes about her medical health in anticipation of this visit, asserting that this was her common practice, and offered these notes into evidence at hearing (although they were never previously identified as existing prior to that moment). Ex. 82 and 83; Tr. at 34-35 ("[i]t is my tradition that I usually take notes . . . things that I need to talk about."), 37-38, 67-68, 78-79.[9] Petitioner testified that she tearfully expressed the above-mentioned problems to Dr. Lara who listened "attentive[ly]" and recommended a follow-up appointment (along with "more testing").[10] Tr. at 39, 78-79. Petitioner otherwise proposed that she may have downplayed how she then felt because she had always been a "very positive person." *Id.* at 40 ("even though I probably felt the way I felt, I knew that a new year was coming and that things . . . w[ere] going to get better").[11]

Following her visit with Dr. Lara in December 2012, Petitioner testified that she scheduled an appointment with Dr. Neira for February 2013 (to discuss her overall condition and symptoms). Tr. at 45. She was unable to keep that appointment, however, due to her onset of GBS. *Id.* Upon further questioning, Petitioner stated that she did not seek an earlier appointment with Dr. Neira because she thought her symptoms of tiredness and voice hoarseness would resolve on their own. *Id.* at 46 ("I felt that they were going to go away because I didn't have a fever, didn't have diarrhea,

[9] On cross, Petitioner attempted to account for the eve-of-trial discovery of this evidence, maintaining that she located the personal health agenda from the Dr. Lara appointment on or about Thursday evening prior to hearing (or August 2, 2018). Tr. at 66. She purported to have been searching for the notes, but had been unable to locate them. *Id.* at 66-67. Petitioner could not explain why she did not bring the agenda to Dr. Lara's deposition, however, or why her January 24, 2015, declaration did not reference their existence. *Id.* at 67.

[10] It is not clear if the additional testing or follow-up were intended to address Petitioner's symptoms related to fatigue or her gynecological symptoms. *See* Tr. at 39.

[11] Given reasonable questions about the discovery of this evidence, I cautioned Petitioner that her personal health agenda/notes would need to be filed and properly authenticated, along with any evidence that would corroborate the date of their creation. Tr. at 94-95, 99. I also asked Petitioner some questions about the manner in which this evidence might have been maintained. In response, Petitioner testified that she typically produced her notes on a personal computer, although she could not access the notes electronically (something that might establish, via a file time stamp, when the document actually was created) because the computer had since crashed. *Id.* at 91, 94.

Following the hearing, on September 11, 2018, Petitioner filed various pieces of evidence attempting to authenticate her notes. Analysis of her hard drive completed by Mr. Chinea confirmed that no data could be retrieved concerning the date the document was created. *See* Ex. 87 at 3. Petitioner also filed examples of similarly created health agendas (some hand written and some typed), as well as a photo of the "pink binder" in which she located the agenda pertaining to Dr. Lara's visit. Tr. at 66; *see* Ex. 84; Ex. 85; Ex. 86 (example of Dr. Neira appointment agenda). Petitioner and her husband otherwise filed additional declarations attesting to the reliability of the above-described exhibits. *See* Ex. 88 and 89.

I didn't have – I was not vomiting, I was not – I just felt really tired, and my voice was raspy. So I thought it's gonna be taken away"). On cross, however, Petitioner acknowledged that she could have scheduled an appointment with Dr. Neira sooner if she had been experiencing a more concerning problem. *Id.* at 68-69.

Petitioner went on to testify about additional occurrences in December 2012-January 2013 that in her view corroborated her allegations of post-vaccination symptoms. In December 2012, Petitioner attended a dinner with friends and family at Outback Steakhouse. Tr. at 46-47.[12] Petitioner described choking on a small piece of meat. *Id.* at 47 ("I couldn't get – dislodge the piece of meat."). Then, over the Christmas holiday, Petitioner described similar feelings of sleepiness/tiredness, along with problems regulating her temperature. *Id.* at 48 ("My hands were cold. My – my legs were cold. My feet were cold."), 49-50. The end of the following month, just prior to her hospitalization, Petitioner recalled attending a book signing event for Dr. Moore (who had written a guide for seeking assisted living care for elderly relatives). *Id.* at 50-51. Mrs. Chinea had been invited to speak at the event, but stated she had trouble completing her speech due to voice irritation. *Id.* at 51 ("My voice was totally – it was gone, was very very raspy, very deep.").

Petitioner presented to the emergency room on January 31, 2013, with complaints similar to those discussed above (including sleepiness, trouble swallowing, and temperature problems). Tr. at 55, 86-88. She testified that she could not walk or stand at the time of arrival, and thus had to be brought into the hospital by wheelchair. *Id.* at 55. She recalled experiencing sleepiness, "shallow breaths[,]" low oxygen, as well as an inability to speak. *Id.* at 55 ("I lost my voice."), 56. As a result, Mr. Chinea was primarily responsible for communicating with her treaters. *Id.* at 58. She was intubated thereafter and experienced additional symptoms (including paralysis). *Id.* at 59.

As already mentioned in the review of the contemporaneous medical records, Petitioner's emergency room intake records set forth that Petitioner had been in her "normal state of health" until roughly one week prior to her January 31, 2013, presentation. Tr. at 60. At hearing, however, Petitioner maintained that such references in the record were inaccurate. *Id.* Rather, Petitioner testified, she had been experiencing milder forms of the symptoms that led to her hospitalization throughout the fall and early winter. *Id.* at 60-61, 63-64. In particular, she denied experiencing allergies, brought on by exposure to a cat in the two weeks before her hospitalization. *Id.* at 61, 63. She also maintained that her "throat" symptoms/voice hoarseness were unrelated. *Id.* at 62-63. At times, however, Petitioner acknowledged that her earlier-in-time symptoms could have been related to her pre-existing allergies/asthma. *Id.* at 83. Overall, apart from her own inability to communicate, Petitioner could not firmly explain the discrepancies in her intake records. *See id.*

[12] Two of Petitioner's other fact witnesses (Mr. Rolando Chinea and Dr. Diane Moore) also attended this dinner. Tr. at 47.

at 61, 88. She assumed that whoever provided her medical history to her ER treaters must have simply been describing "how [she] used to be" (presumably *prior* to her alleged onset of symptoms in November 2012), rather than providing a truthful assessment of the start of the severe symptoms in January. *Id.* at 88.

B. *Mr. Rolando Chinea*

Petitioner's second fact witness was her husband, Mr. Rolando Chinea. Tr. at 124-160. He also filed two witness declarations. *See* Ex. 56 & 67.[13] Mr. Chinea is an electrical engineer. Tr. at 124. He graduated from the University of Puerto Rico in 1979, and moved to the United States that same year to take a job with the Department of Defense. *Id.* at 125. Mr. Chinea met Petitioner in 1970, and they were married in 1976 (prior to their move). *Id.* at 125-26. In addition to his primary employment, Mr. Chinea assists Petitioner with her duties at Alma Joy Villa. *Id.* at 156-57. In particular, he often handles evening or overnight responsibilities at the care facility given the workload and small staff. *Id.* at 157-58.

Mr. Chinea described Petitioner as energetic, organized, and warm-hearted. Tr. at 127. Prior to receipt of the flu vaccine in October 2012, Mr. Chinea testified that Petitioner's "energy level was very high." *Id.* at 128 ("[s]he used to go walking, dancing, to the gym almost daily, and she was always like the [energizer] bunny rabbit, you know, going – moving and helping people and – all the time"). Petitioner's typical day began around 5:00 AM (and included both a trip to church and the gym as well as assisting with breakfast and household tasks). *Id.* at 128-29. She would then go to work, where Mr. Chinea testified she was "more than active" and successfully managed both hospital duties and staff management. *Id.* at 129.

Following vaccine administration, however, Mr. Chinea began to notice a change in Petitioner's energy level starting in early November 2012. Tr. at 130, 143. She expressed feelings of cold, slept for long hours, and attended gym classes less often. *Id.* at 144. She also mentioned a "lack of sensation" in her hands, fingers, arms, and legs. *Id.* Petitioner's already low energy level worsened that Thanksgiving, and resulted in her not participating in the holiday as she had in the past. *Id.* at 129-30, 132. She also began requesting assistance with various household tasks (including opening jars or lifting items to and from the stove). *Id.* at 130, 131 ("[s]he didn't have the strength or the stamina to go [to the grocery store]"). These symptoms progressed through the Christmas holiday. *Id.* at 132-33. Petitioner also reported experiencing vision problems. *Id.* at 145 ("I had to change the size of the font [on the computer] because she couldn't read properly.").

[13] At hearing, Mr. Chinea acknowledged that Petitioner reviewed and edited his two witness statements. Tr. at 142-43. He maintained, however, that any corrections she would have made were merely grammatical in nature. *Id.* at 143. He seemingly denied knowing if any such changes were made. *Id.*

Mr. Chinea also testified about Petitioner's December 10, 2012, appointment with Dr. Lara. Tr. at 134. He maintained it was likely he had traveled with Petitioner to the appointment, but added that he was not present for any conversation between Dr. Lara and Petitioner regarding her purported symptoms at the time. *Id.* at 134-35, 136.[14] Mr. Chinea did, however, confirm that Petitioner likely would have taken medical notes along with her to discuss with Dr. Lara (as this was her typical practice). *Id.* at 135. Regarding the health agenda produced by Petitioner at hearing, Mr. Chinea acknowledged that Petitioner had only recently located it. *Id.* at 147-48. He also confirmed that it was common for her to prepare written notes about her health status and symptoms, and then later to transfer them to the home computer. *Id.* at 147.

Upon Petitioner's presentation to the emergency room on January 31, 2013, Mr. Chinea was the primary historian during the visit (as Petitioner was having difficulty talking and communicating to hospital personnel). Tr. at 137; *see also* Ex. 67 at 3. Mr. Chinea testified that he informed hospital personnel that Petitioner had received the flu vaccine that year. Tr. at 138-39. He also took copies of Petitioner's medical records to the ER. *Id.* at 149. Mr. Chinea described Petitioner as in "really bad shape." *Id.* at 137. She was "unbalanced" and could not walk unassisted. *Id.* Mr. Chinea also recalled some breathing troubles and voice hoarseness prior to Petitioner's presentation. *Id.* at 137-38.

Mr. Chinea denied telling hospital personnel what the contemporaneous records indicate he said: that Petitioner had been in her "usual state of health" in the days prior to presentation (or before January 28th). Tr. at 138-39. He reported instead that her health had been in decline since November of that year, although she previously always had been a healthy person (and thus suggesting, as Mrs. Chinea did, that these record references inaccurately confused her pre-vaccination health with her symptoms in the weeks before hospitalization). *Id.* at 139, 140. Thus, Mr. Chinea disputed the accuracy of notations in the contemporaneous record that suggested that Petitioner had been exercising as normal before the ER visit. *Compare* Tr. at 139 ("[s]he went to the gym, did one hour samba and one hour walking in her neighborhood") *with* 140 ("that statement there is not accurate"). Rather, such descriptions applied to Petitioner's pre-vaccination circumstances, "*not* in January or in December of that year." *Id.* at 140 (emphasis added).

[14] There was some confusion at hearing regarding whether in fact Mr. Chinea took Petitioner to the December 10th visit with Dr. Lara. On cross, Mr. Chinea acknowledged that it was possible that a friend had taken her to the appointment, and that he had transported her to a follow-up appointment thereafter. Tr. at 153-55. He later maintained that he had taken her to the December 10th appointment. *Id.* at 155-56. His witness statement, however, was somewhat unclear. The statement suggests that an unspecified friend took Petitioner to an appointment with Dr. Lara "in early December." Ex. 56 at 7. That same statement noted that Mr. Chinea "had to drive her to *other* appointments at this time." *Id.* at 7 (emphasis added).

In the same vein, Mr. Chinea sought to clarify some of his statements (contained in the contemporaneous medical record) regarding Petitioner's cat allergy, and a particular reaction she may have experienced just before her hospitalization. Tr. at 140-41. Mr. Chinea recalled Petitioner's visit to the home of a potential Alma Joy Villa client a few days prior to the ER presentation, at which time Petitioner experienced an adverse reaction to a cat inside the home. *Id.* at 141. According to Mr. Chinea, Petitioner had something like an "asthma attack" accompanied by additional symptoms (including an inability to talk, walk, or sit down). *Id.* Given the emergent nature of Petitioner's hospital presentation, Mr. Chinea informed treaters of the above-mentioned event due to its proximity in time to her hospitalization. *Id.* at 150-51. Notably, Mr. Chinea acknowledged that he did not also report Petitioner's purported November/December symptoms to treaters at that time because he had not "connect[ed] the dots" between the flu vaccine and her downward progression at that point. *Id.* at 151.

Following Petitioner's ER visit, Mr. Chinea conducted his own research concerning Petitioner's GBS diagnosis and whether the disease might be vaccine-related. Tr. at 159-60; Ex. 56 at 5-6. At hearing, Mr. Chinea stated that he suspected the flu vaccine initially because Petitioner's testing for traditional triggers revealed no explanation. Tr. at 159. Despite the above, Mr. Chinea confirmed that his research was prompted only by his desire to find a possible explanation for his wife's symptoms. *Id.* He otherwise asserted that the research he individually performed occurred in the weeks following Petitioner's hospital presentation, and he presented his concerns to Petitioner's treaters thereafter. *Id.*

C. *Dr. Arturo Sidransky*

Petitioner's next witness was Dr. Arturo Sidransky. He testified at hearing and offered witness declarations in support of Petitioner's assertions concerning her overall health progression from November 2012 to her hospital presentation in January 2013. Tr. at 103-23; Ex. 57 (Declaration of Dr. Sidransky).[15]

Dr. Sidransky is medical doctor with over forty years of practice experience. Tr. at 104. He graduated from the University of New Mexico Medical School and thereafter completed an internship in obstetrics/gynecology and a fellowship in emergency medicine. *Id.* Dr. Sidransky first met Petitioner in 1979-80 while employed at St. John's Regional Medical Center in Oxnard, California, when he attended to Petitioner's daughter during an emergency room visit. *Id.* at 104-05. The families thereafter became social friends. *Id.* During that time period, Petitioner worked

[15] At hearing, Dr. Sidransky acknowledged that Petitioner requested he author the above-mentioned declaration *prior* to her filing of this matter. Tr. at 114-15. He otherwise stated, however, that his declaration was solely his work (i.e., he did not use notes or explanations provided by Petitioner to aid him in writing drafts or the finalized version). *Id.* at 115-16.

in the education department at St. John's and Dr. Sidransky would participate in health programs sponsored by Petitioner and other staff members. *Id.* at 105-06. Dr. Sidransky's mother later became a resident of Alma Joy Villa. *Id.* at 106. Dr. Sidransky testified that he sees Petitioner on a weekly basis (or more often). *Id.* at 107.

Prior to her hospitalization in January 2013, Petitioner was "vivacious" or the "life of the party." Tr. at 109-10. It was for these reasons that Dr. Sidransky entrusted his mother's care to Petitioner and her staff. *Id.* But (and in contrast to how she had typically acted at prior Thanksgivings), Petitioner was in his view noticeably different in November 2012. *Id.* at 107-08, 111. Dr. Sidransky specifically recalled Petitioner stating she was "hurting" and had low energy and arm pain. *Id.* at 111; Ex. 57 at 4 (declaration regarding arm pain). Her voice was also "raspy and muffled." Tr. at 111. On cross, Dr. Sidransky acknowledged that he did not really delve into the nature of Petitioner's concerns at the time (i.e., he did not make recommendations for treatment or discuss the symptoms with her). *Id.* at 116. He also noted that at this time Petitioner appeared to have a normal appetite and gait. *Id.*

Dr. Sidransky next discussed two social outings during the month of December 2012, which in his view further evidenced Petitioner's adverse symptoms. He recalled a holiday party at a Greek restaurant where families gathered for dancing. Tr. at 111-13. Petitioner, however, refused an invitation to the event due to low energy. *Id.* at 112. Dr. Sidransky also recalled his wife's birthday party in mid-December 2012. *Id.* at 112-13. Petitioner attended this event, but would not participate in activities due to an inability to concentrate and persistent low energy. *Id.* at 112 ("we played cards – but [Petitioner] didn't feel that she had the energy or would be able to concentrate to play cards, so she refused to play with us").

Dr. Sidransky also discussed Petitioner's January 2013 hospital presentation and her symptomatology course leading up to the GBS diagnosis. At hearing, Dr. Sidransky testified that he examined Petitioner some time in the days *prior* to her hospital presentation (though, he could not identify the exact date). Tr. at 118. Petitioner's husband had called him and asked that he visit Petitioner at home due to her various adverse symptoms (including tiredness, watery eyes, a muffled voice, a flushed face, and an inability to sit up or get out of bed). *Id.* at 119. Dr. Sidransky recalled that Petitioner did not complain of pain, and her physical exam was otherwise normal apart from the above-noted complaints. *Id.* He did not test her reflexes at that time. *Id.* Dr. Sidransky recommended that Petitioner's husband take her to the emergency room if her condition worsened. *Id.* He otherwise could not recall *when* Petitioner began to experience the symptoms noted above.

Dr. Sidransky subsequently went to see Petitioner on January 31, 2013 (the day she presented to the hospital), and discussed her condition with hospital treaters. Tr. at 113. Dr.

Sidransky recalled that Petitioner was intubated upon presentation, and had minimal movement in her hands and feet. *Id.* ("she couldn't move a toe . . . [s]he couldn't move a finger"). He also spoke with Petitioner's intake neurologist at the time, who informed him that Petitioner likely had GBS secondary to the flu vaccination she received in October 2012. *Id.* at 114, 122; *see also* Ex. 57 at 5. Later, however, Dr. Sidransky acknowledged he was unsure how he found out about Petitioner's prior receipt of the flu vaccine (i.e., Petitioner or her husband may have told him at some point). Tr. at 120, 122-23. Dr. Sidransky's declaration (filed as Ex. 57) stated that *he* actually informed Petitioner's hospital treaters that she received the shot in October of the previous year. Ex. 57 at 5 ("I related to them about her having the vaccine."). He otherwise stated that he was not involved in Petitioner's care during or after her GBS diagnosis. Tr. at 122.

D. *Ms. Enjoli Flores*

Petitioner's next fact witness was Ms. Enjoli Flores. She testified at hearing and offered witness declarations in support of Petitioner's assertions regarding the onset of her symptoms. Tr. at 161-80; Ex. 66.[16]

Ms. Flores moved to the United States in 2006 from Puerto Rico. Tr. at 161. She met Petitioner in July 2012 (roughly three months prior to her receipt of the flu vaccine) at a fitness club. *Id.* at 162. Ms. Flores recalled that she and Petitioner shared many common interests (such as attending dancing classes and religious services, and having lunch or dinner together). *Id.* at 162-63. Ms. Flores testified that from July to October 2012, she routinely interacted with Petitioner three to four times per week. *Id.* at 164. She described Petitioner as full of energy. *Id.* at 163, 165-66. In her view, Petitioner was always happy and active in managing her many responsibilities (including the family, gym, her job, and church). *Id.* at 165-66.

Consistent with the fact testimony discussed earlier, Ms. Flores recalled that Mrs. Chinea began to change around mid-November 2012. Tr. at 167-68. Ms. Flores spoke with Petitioner on the phone in early November 2012 to discuss holiday preparations, and she did not recall complaints of low energy around that time. *Id.* at 77. Thereafter, however, Petitioner began to exhibit exhaustion just prior to the Thanksgiving holiday. *Id.* at 168, 170. Ms. Flores recalled a specific instance at a fitness class where Petitioner complained of left arm pain and exited the class early. *Id.* at 169. Ms. Flores also discussed a time around November 20, 2012, when she kept Petitioner's granddaughter while she attended a doctor's appointment. *Id.* at 170, 177. Ms. Flores testified that Petitioner was experiencing voice hoarseness around the time of this appointment. *Id.*

[16] On cross, Ms. Flores testified that she sent drafts of her declaration to Petitioner for her review. Tr. at 174-75. Ms. Flores recalled that Petitioner offered suggestions/edits regarding her recollection of Petitioner's health in December 2012 (specifically in the context of Petitioner's refusal to attend Ms. Flores's birthday party). *Id.* at 174. She did not remember if Petitioner offered suggestions regarding any other portion of her declaration. *Id.* at 175.

at 170. On cross, however, Ms. Flores could not recall if Petitioner complained of any other symptoms or what type of doctor she saw. *Id.* at 177. She remembered only that Petitioner wasn't feeling well and that the symptoms had not resolved. *Id.* at 178.

For Thanksgiving that year, Petitioner had planned to host a meal at her home (and cook for a local homeless shelter), but the plans fell through due to her health. Tr. at 168. Ms. Flores recalled that she attended a Thanksgiving meal at the home of a different friend instead. *Id.* at 170-71. During the meal, Ms. Flores described Petitioner as quiet and tired. *Id.* at 171 ("she wasn't talking or being part as she was used to being, so quiet"). On cross, she also stated that Petitioner had trouble walking (i.e., she was walking "slowly"). *Id.* at 175. Ms. Flores did not recall, however, that Petitioner needed assistance serving her plate. *Id.*

The symptoms described above continued into December 2012. Tr. at 171-72. Ms. Flores recalled that Petitioner refused an invitation to her birthday party in mid-December due to sickness symptoms (including congestion and breathing troubles). *Id.* She also recalled a time in early January 2013, when Petitioner visited her home. *Id.* at 172. Ms. Flores was pregnant, and Petitioner was helping her prepare for the baby's arrival. *Id.* At the visit, Ms. Flores recalled Petitioner looking tired and weak. *Id.* Petitioner also refused an offer to stay for lunch because she wanted to go home and rest. *Id.* On cross, Ms. Flores noted that she was not concerned about the January 2013 symptoms because Petitioner told her she was not contagious. *Id.* at 176. She could not, however, offer details regarding any additional wellness appointments or other explanation for why Petitioner would know her symptoms were not concerning. *Id.*

E. *Dr. Diane Moore*

Petitioner's final fact witness was Dr. Diane Moore. She testified at hearing and offered witness declarations detailing Petitioner's adverse symptoms in the months leading up to her GBS diagnosis. Tr. at 180-207; Ex 55.[17]

Dr. Moore is an English professor at Ventura Community College in Ventura, California. Tr. at 181. She became acquainted with Petitioner while searching for a residential care facility for her elderly mother. *Id.* at 182. Dr. Moore stated that she chose Petitioner's facility for her mother due in part to Petitioner's extensive background in senior living and her overall enthusiasm for the work. *Id.* Dr. Moore's mother has been a resident at Alma Joy Villa since May 2010. *Id.* Because of Petitioner's extensive involvement in her mother's daily care, Dr. Moore communicated with

[17] Dr. Moore testified that she wrote multiple drafts of her statement before the present matter was filed. Tr. at 200-01. She denied, however, that her drafts were shared with Petitioner (or others), and maintained that she had no input from Petitioner or her family and friends. *Id.*

Petitioner (either telephonically or in-person) almost daily between May 2010 and October 2012. *Id.* at 183.[18]

Dr. Moore described Petitioner as "extremely energetic," organized and involved in her community. Tr. at 186 ("[she] was a dynamo"), 187. Petitioner was dedicated to her work at Alma Joy Villa and would engage personally in the care of each resident. *Id.* at 187. She also encouraged family members to participate in residential activities. *Id.* By early November 2012, however, Petitioner was not often at the facility when Dr. Moore visited, and voiced concerns regarding her health (including voice hoarseness, tiredness, and achiness) during their phone conversations. *Id.* at 188, 203. Dr. Moore also recalled a time in mid-November of that year when Petitioner failed to show for a scheduled meeting regarding her mother's care. *Id.* at 190. According to Dr. Moore, during a phone conversation thereafter, Petitioner explained that she was not feeling well and missed the meeting because she had fallen asleep. *Id.* at 191. Though Dr. Moore did not see Petitioner personally at this time, she recalled that Petitioner was still experiencing voice hoarseness and weakness. *Id.* At some point during their discussions in November 2012, Dr. Moore also testified that Petitioner complained of persistent swelling in her arm following a flu vaccination. *Id.* at 188.

Dr. Moore testified that Petitioner's adverse symptoms continued into the Thanksgiving holiday. Tr. at 192. In prior years, Dr. Moore recalled, Thanksgiving at Alma Joy Villa was a "fiesta" with beautiful decorations and a complete Thanksgiving dinner. *Id.* at 187-88. Petitioner was "the life of the party" and created a celebratory environment for both residents and their families. *Id.* at 188. Thanksgiving 2012, however, was "dramatically different." *Id.* at 192. Petitioner ordered a precooked holiday dinner that year, and the facility was not decorated. *Id.* at 192-93. Dr. Moore described Petitioner as "exhausted" and "quiet." *Id.* at 193. Her eyes were "dull" and "lackluster." *Id.* When asked about the above-mentioned behavior, Petitioner stated that she did not feel well. *Id.*

Thereafter, in December 2012, Dr. Moore expressed concerns regarding Petitioner's health and its effect on her management of Alma Joy Villa (especially in the context of patient/caregiver communication). Tr. at 194. For example, Dr. Moore noticed that Petitioner was not at the facility as much when she visited her mother. *Id.* at 193-94. Dr. Moore scheduled a meeting with Petitioner to address these concerns. *Id.* at 194-95. During the meeting, Petitioner apologized and explained that she "wasn't up to being there like she had before." *Id.* at 195. Petitioner agreed to communicate more regularly by phone with caregivers and staff. *Id.*

[18] To prepare for hearing, Dr. Moore relied in part on a detailed diary of calendars she kept regarding her mother's care. These diaries included specific dates that she met with Petitioner and/or visited the Alma Joy Villa facility. Tr. at 184-86.

Petitioner's symptoms continued through the 2012 Christmas season. Tr. at 195. Like the Alma Joy Villa Thanksgiving celebration that year, the Christmas party was less festive than in prior years. *Id.* By this time, Petitioner had become more "lethargic" and "seemed weak." *Id.* Following the Christmas party, Dr. Moore recalled a social outing with the Chineas in late December 2012. *Id.* at 196. Dr. Moore and her mother treated the Chineas to dinner at Outback Steakhouse to thank them for their hard work that year. *Id.* They also planned to attend a musical theater performance at the local college after dinner. *Id.* During the dinner, Dr. Moore recalled Petitioner was still experiencing voice hoarseness (and did not seem to be enjoying herself). *Id.* at 196, 206. She also choked on her food. *Id.* at 196, 197 ("as we were eating, [Petitioner] started gasping for breath and choking . . . . [but] eventually breathed").

Moving to early January 2013, Dr. Moore recalled an instance where Petitioner canceled a scheduled meeting. Tr. at 197. Dr. Moore had planned to discuss her mother's medication, but Petitioner called to say she wasn't feeling well. *Id.* ("she wasn't up to coming to the facility, and . . . [h]er voice was much more hoarse and weak"). The two spoke by phone instead. *Id.* Dr. Moore next recalled Petitioner's demeanor at her mother's birthday party at Alma Joy Villa in mid-January 2013. *Id.* at 197-98. According to Dr. Moore, Petitioner was not involved in the party planning (which was unusual) and arrived over one hour late because she had fallen asleep. *Id.* at 198. Dr. Moore also described a book signing event she and Petitioner attended together. *Id.* at 198-99. Dr. Moore had authored a book on the topic of senior assisted living, and she invited Petitioner to speak at the signing event. *Id.* at 198. During the event, Dr. Moore recalled that Petitioner could not complete her planned speech due to voice hoarseness. *Id.* at 199. She also lacked her usual "sparkle." *Id.*

F. *Additional Declarations*

Besides the hearing testimony offered by the above-noted fact witnesses, Petitioner filed five declarations from other family members and professional/social acquaintances in attempts to bolster her claim that she was experiencing GBS-related symptoms beginning in November 2012. *See* Ex. 61 (Declaration of Tom Hovarth) ("Hovarth Dec."); Ex. 62 (Declaration of Linda Neilson) ("Neilson Dec."); Ex. 63 (Declaration of Carmen Garay) ("Garay Dec."); Ex. 64 (Declaration of Doris Calderon) ("Calderon Dec."); Ex. 65 (Declaration of Astrid Carrillo) ("Carrillo Dec.").

The statements provided by the above-named individuals are consistent with the fact witness testimony offered at hearing. In short, Petitioner was noted to have decreased energy during the early weeks of November 2012 (which continued thereafter through December of that year). Hovarth Dec. at 4; Neilson Dec. at 4; Garay Dec. at 4; Calderon Dec. at 4; Carrillo Dec. at 5. Multiple statements also referenced additional adverse symptoms Petitioner experienced throughout those months, including: voice troubles, arm pain, fatigue, low stamina, shortness of

breath, exhaustion, and loss of appetite. Hovarth Dec. at 4; Neilson Dec. at 4; Garay Dec. at 4; Calderon Dec. at 4; Carrillo Dec. at 6-7. Many expressed confusion as to what caused Petitioner's symptoms (as she had reported to them that she had not experienced any new onset health complications or altered her routine in any way). Hovarth Dec. at 4; Neilson Dec. at 4; Garay Dec. at 5.

One statement in particular (from Tom Hovarth) noted that Petitioner had expressed some concern that her flu vaccination might have precipitated her adverse symptoms. Hovarth Dec. at 4. The statement also indicated that Mr. Hovarth was "against flu shots, pneumonia, etc., that government agencies perpetrate on us on a yearly basis." *Id.* at 4. Mr. Hovarth's statement did not indicate what prompted Petitioner to suspect the vaccine, however, or when these discussions occurred.[19] Mr. Hovarth did state that Petitioner was also against receiving the flu vaccine, but did so because it was required by the state of California given her occupation as a health facility administrator. Hovarth Dec. at 4.

III. Expert Testimony

A. *Petitioner's Expert – Dr. Lawrence Steinman*

Dr. Steinman prepared two written reports for this case and testified at hearing. Tr. at 213-300, 355-62; Expert Report, dated Aug. 19, 2015 (ECF No. 31-1) ("First Steinman Rep"); Expert Report, dated Feb. 15, 2017 (ECF No. 64-1) ("Steinman Supp. Rep."). He offered the opinion that the flu vaccine Petitioner received in late October 2012 was the cause of her GBS, and that the symptoms she experienced in November and December of 2012 were associated with her illness, even though her symptoms did not become acute until late January 2013 (almost three months after vaccine administration). Tr. at 218.

Dr. Steinman obtained his medical degree from Harvard Medical School, where he completed a fellowship in chemical neurobiology. Tr. at 214; *see also* CV, filed as Ex. 76 (ECF No. 74-1) ("Steinman CV") at 1. After medical school, Dr. Steinman went on to complete both a pediatrics and neurology residency at Stanford University. Tr. at 214; Steinman CV at 1. He then joined the faculty at Stanford in 1980, where he presently serves as the George A. Zimmerman Professor of Neurological Sciences, Neurology, Genetics and Pediatrics. Tr. at 216; Steinman CV at 1. During his tenure, Dr. Steinman estimated that he has treated multiple patients with various diseases, including MS, GBS, and/or ADEM. Tr. at 215. Dr. Steinman has also published

[19] The declaration indicated that Mr. Hovarth noticed a change in Petitioner's disposition "[i]n the beginning of November 2012, around the week of the 12th." Hovarth Dec. at 4. Presumably his conversation with her happened around this time, although the declaration does not give a specific date. *See id.*

extensively in peer-reviewed journals on topics including neuroimmunology and GBS. Steinman CV at 5-46. He is an exceedingly qualified expert on the subjects at issue in this case, and has testified numerous times in the Vaccine Program.

To begin, Dr. Steinman reviewed Petitioner's symptoms and the progression of her condition compared to the most common features of GBS. Tr. at 218-19. The relevant literature cited by Dr. Steinman describes GBS as an autoimmune disease in which the immune system essentially attacks components of the peripheral nerves, leading to acute (or rapidly progressive) flaccid symmetrical weakness of the limbs (including paresthesia and sometimes pain). *See, e.g.*, J. Menze, et al., *Textbook of Peripheral Neuropathy* 167 (1st ed. 2012), filed as Ex. 80 (ECF No. 74-5) ("Menze") A typical course can also include generalized weakness, sensory disturbances (i.e., tingling), pain, unsteady gait, and loss of bowel function. *Id.* The disease is diagnosed using an array of diagnostic testing (including a physical exam, CSF analysis, nerve conduction studies, and MRI imaging). *Id.* at 168. The precise trigger of the disease is unknown, but it is thought to be often precipitated by a respiratory or gastrointestinal infection. *Id.* at 167.

GBS has different variants. Dr. Steinman categorized Petitioner's GBS as the Miller-Fisher variant (consistent with the medical record evidence filed in the case). Tr. at 218; First Steinman Rep. at 1.[20] A typical course associated with this variant can include eye movement abnormalities and ataxia (due to the involvement of the brainstem's peripheral nerves), along with the other more traditional manifestations of GBS identified above. Tr. at 218, 239. Notably, the Miller-Fisher variant is also associated with a particular antiganglioside antibody: the GQ1B antibody. *Id.* at 219-20. Dr. Steinman relied heavily on Petitioner's medical record in confirming the above-noted GBS diagnosis. As those records revealed, Petitioner presented to the emergency room in late January 2013 with generalized weakness, muscle soreness, shortness of breath, and absent deep tendon reflexes (along with an associated cough/congestion and voice hoarseness). First Steinman Rep. at 4-5; Ex. 7 at 1-2. A lumbar puncture test conducted on February 1, 2013, supported the GBS diagnosis. First Steinman Rep. at 5; Ex. 7 at 1. Petitioner also tested positive for the GQ1B antibody. Tr. at 219-20.

Dr. Steinman next discussed Petitioner's health history prior to her hospital presentation on January 31, 2013, and its purported relationship to her eventual diagnosis. In his view, Petitioner exhibited multiple GBS-related symptoms in the months *prior* to her hospitalization, beginning as

[20] In so opining, Dr. Steinman attempted to refute some suggestion by Dr. Donofrio (Respondent's opining expert) that Petitioner's condition was best characterized as brainstem encephalitis. Tr. at 266-67, 297. He agreed that the medical record revealed some evidence that Petitioner had experienced "neuro-inflammation" or "inflammation in the brainstem," but maintained the record best supported a diagnosis of GBS. *Id.* at 270. In any event, Dr. Donofrio accepted GBS to be the diagnosis best supported by the medical record at hearing. *Id.* at 307, 329.

early as Thanksgiving 2012 (including double vision, overwhelming fatigue, taste disturbance,[21] voice hoarseness, feelings of tingling/cold, and swallowing difficulties). Tr. at 234-40. These symptoms, he asserted, were likely due to inflammation in the various nerves in and around the brainstem. *Id.* at 296.

In Dr. Steinman's opinion, Petitioner's "overwhelming fatigue" was likely due to inflammation occurring congruently with the underlying nerve damage initiated by the autoimmune process that ultimately resulted in a GBS diagnosis. Tr. at 236 ("if your nerves aren't functioning well, doing the activities of daily living just takes so much more energy"). Voice hoarseness (as described by Petitioner and her fact witnesses), in his view, could also be caused by the "impact of inflammation" on nerves controlling the larynx and vocal cords. *Id.* at 240. Similarly, tingling could be a consequence of inflammation in the peripheral nerve "between its root and the distal portion." *Id*. Dr. Steinman opined that Petitioner's swallowing problems were likely due to inflammation in the cranial nerve (although he allowed for the possibility that the fatigue or hoarseness she was experiencing could have played a role in the swallowing issues). *Id.* at 241. Petitioner's feelings of cold/chilliness, by contrast, were in Dr. Steinman's experience atypical of the GBS patients he has treated over the course of his career. *Id.* at 240-41. Nevertheless, he allowed for the possibility that cool feelings could be a result of underlying inflammation as well. *Id*. at 240. Dr. Steinman did not find it concerning that Petitioner had no associated fever around this time. *Id*. at 296.

To support linking the fall 2012 symptoms to Petitioner's later and more obvious GBS onset, Dr. Steinman cited various scientific articles detailing the common symptoms associated with a GBS course. *See, e.g.,* A. Langmuir, et al., *An Epidemiologic and Clinical Evaluation of Guillain-Barre Syndrome Reported in Association with the Administration of Swine Flu Influenza Vaccines*, 119 Am. J. Epidemiology 841, 847-48 (1984), filed as Ex. 45 (ECF No. 32-8) ("Langmuir") (noting typical *presenting* clinical criteria for GBS can include progressive motor weakness, paralysis of the extremities plus trunk and/or cranial muscle involvement, bilateral neurologic signs, lower motor neuron signs, areflexia, and autonomic dysfunction); L. Schonberger, et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. Epidemiology 105, 117 (1979), filed as Ex. 44 (ECF No. 32-7) ("Schonberger") (respiratory impairment, trunk/cranial involvement, and sensory symptoms could also be associated with a GBS diagnosis). The above-mentioned articles did not, however, offer the same level of specificity as Dr. Steinman's opinion.

[21] Dr. Steinman did not reference any literature supporting his contention that taste disturbance was associated with GBS. Tr. at 236-37. He maintained, however, that the relevant scientific literature supports such a conclusion. *Id.*

Along the same lines, Dr. Steinman challenged Dr. Donofrio's assertion that many of the above-mentioned symptoms (specifically, voice hoarseness, difficulty swallowing, double vision, or light sensitivity) were *not* common presenting indicia of GBS. Tr. at 277-78.[22] Rather, he asserted (albeit in a conclusory manner) that his own "experience" as a practicing neurologist suggested that Petitioner's persistence of symptoms was attributable to inflamed cranial nerves associated with her GBS course. *Id.* On cross, however, Dr. Steinman could not say what criteria he drew upon to characterize Petitioner's overall constellation of symptoms as falling within GBS. *Id.* at 285. In addition, when confronted with certain GBS diagnostic criteria *not* evidenced in Petitioner's history prior to her January 2013 hospital presentation (extremity paralysis, for example), Dr. Steinman seemingly categorized Petitioner's case as an "exception" to the typical presentation, but offered no further explanation for the absence of certain normally-presenting criteria discussed in Schonberger/Langmuir (i.e., paresthesia/paralysis of the extremities, plus involvement of trunk/cranial muscle). *Id.* at 289-90.

Dr. Steinman next proposed a mechanism by which the flu vaccine could have caused Mrs. Chinea's GBS: the biologic process of molecular mimicry. Tr. at 230; First Steinman Rep. at 8-14. His testimony on this point revolved around a concept that has been largely accepted in the medical community (and often in the Vaccine Program as well): that antibodies produced to fight off a foreign infectious antigen (or generated in response to a vaccine) can mistakenly attack, or cross-react with, myelin basic protein ("MBP"), a primary protein component of human nerves. As a result, an autoimmune process begins, encouraging the production of antibodies that erroneously attack self-cells and structures, and thereby causing damage to the nerve's myelin sheath. Tr. at 219, 221-22; *see also* L. Steinman, *Autoimmune Disease*, Scientific American 107 (1993), filed as Ex. 34 (ECF No. 31-4). Dr. Steinman's expert report provided a highly detailed walkthrough of possible mimics between protein sequence components contained in the flu vaccine and MBP. First Steinman Rep. at 8-14.

As an example of the molecular mimicry concept, Dr. Steinman briefly discussed the relationship between a particular bacterial infection and onset of GBS. Tr. at 224-26. All forms of GBS, Dr. Steinman testified, are autoimmune diseases occurring after the body mounts an immune response to a foreign agent that accidently targets the body's own nerve tissue. *Id.* at 222. One of the most well-known examples of molecular mimicry resulting in such an autoimmune process involves a structure shared between a bacterium called *Campylobacter jejuni* and gangliosides - sugar structures found on the surface of myelin. *Id*. at 224, 226. Dr. Steinman opined that it is medically accepted (while not fully understood) that certain vaccines can also

[22] For example, Dr. Donofrio suggested Petitioner's swallowing problems could be evidence of GERD. Dr. Steinman did not find this assertion credible, given that Petitioner's record evidenced a GERD diagnosis no earlier than April 2015 (over two and one-half years post-vaccination). Tr. at 272. He otherwise attempted to recast the assertion by claiming that GBS is not associated with GERD. *Id.*

cause GBS, initiating an autoimmune process the same way microbe (like the *Campylobacter* bacterium) might. *Id*. at 224. The components of the vaccine actually share molecular homologies with myelin structures present in the human body, and thus could produce the same reaction as a wild virus alone. *Id.*

Dr. Steinman theorized that Petitioner's GBS was likely initiated by the hemagglutinin component[23] of the 2012 Fluvirin form of the flu vaccine. Tr. at 220, 223; First Steinman Rep. at 11-12. He maintained that this component is known to trigger/induce antiganglioside antibodies, specifically the anti-GQ1B associated with the Miller-Fischer variant of GBS, via a cross-reactivity response. Tr. at 220, 223, 225; First Steinman Rep. at 12; *see* I. Nachamkin, et al., *Anti-Ganglioside Antibody Induction by Swine (A/NJ/1976/H1N1) and Other Influenza Vaccines: Insights into Vaccine-Associated Guillain-Barre Syndrome*, 198 J. Infect. Disease 226 (2008), filed as Ex. 39 (ECF No. 32-2) ("Nachamkin"). In Nachamkin, researchers determined that the hemagglutinin component of the H1N1 vaccine had induced the production of anti-GQ1B antibodies in mice, further supporting their overall conclusion that the H1N1 vaccine can induce GBS in this manner. Nachamkin at 226-27.

Given that Petitioner tested positive for the anti-GQ1B antibody and had received a flu vaccine containing hemagglutinin protein, Dr. Steinman found it reasonable to conclude that the H1N1 vaccine she received triggered her onset of related fatigue symptoms (and "somnolence" associated with an increase in anti-GQ1B). Tr. at 219-20; First Steinman Rep. at 13-14; *see* Y. Fukami, et al., *Anti-GQ1B Antibody Syndrome: Antiganglioside Complex Reactivity Determines Clinical Spectrum*, 23 Eur. J. Neuro. 320 (2016), filed as Ex. 41 (ECF No. 32-4) (confirming that elevated levels of anti-GQ1B antibodies can result in ataxia, neck/arm/leg weakness, and hypersomnolence). According to Dr. Steinman, antiganglioside antibodies can mount in a timeframe of days (typically seven to ten), and can thereafter exist in the body for months following production. Tr. at 356.

Apart from the above, Dr. Steinman otherwise asserted that various treater statements contained in Petitioner's records confirmed his suspicion that her receipt of the flu vaccine had precipitated GBS. Tr. at 227-28, 233. Dr. Neira (Petitioner's primary care provider), for example, speculated that Petitioner's GBS was vaccine-induced. *Id.* at 227 (citing Ex. 1 at 7, 73, 77). Dr. Steinman acknowledged that treater statements are not direct proof that a flu vaccine can cause GBS, but he nonetheless felt such statements "carrie[d] a lot of weight" in formulating an opinion by the Program's preponderant standard. *Id.* at 228. He also cited to the flu vaccine package insert as supportive of an association between the vaccine and GBS. *Id.* at 227.

[23] At hearing, Dr. Steinman categorized this component as H1N1 California 2009. Tr. at 220. He defined hemagglutinin is the "outer coat" of the influenza virus. *Id.* at 228.

Dr. Steinman next proposed a medically reasonable timeframe for a flu vaccine-induced GBS injury. In his view, the relevant scientific literature supported an onset as reasonably occurring within a period of a few weeks to up to three months post-vaccination. Tr. at 295 ("four months is too long . . . [but] three months I'd say is ok").[24] In support, he cited to Schonberger and Langmuir. *Id.* at 244-45; *see* Schonberger at 105 (five- to ten-week onset is medically appropriate); Langmuir at 841 (elaborating on Schonberger and determining that a six- to eight-week onset is more typical). In his view, however, the above timeframes are not absolute, but rather provide only a "useful yardstick" in estimating the typical progression of a vaccine-induced injury. Tr. at 246-47, 257. Since researchers in Schonberger/Langmuir studied the 1976 swine flu vaccine specifically, Dr. Steinman felt it would be inappropriate to discount a longer onset for the version of the vaccine administered today. *Id.* at 247, 257.

Besides such admittedly older literature, Dr. Steinman also referenced a more recent article that he had co-authored. Tr. at 221-22; *see* S. Ahmed, et al., *Antibodies to Influenza Nucleoprotein Cross-React with Human Hypocretin Receptor 2*, 7 Sci. Transl. Med. 1 (2015), filed as Ex. 33 (ECF No. 31-3) ("Ahmed"). Ahmed researchers conducted a study which established that the Pandemrix version of the flu vaccine (administered solely in Europe) contained high amounts of a nucleoprotein component associated with narcolepsy, causing that condition by interfering with certain hypocretin receptors in the brain. Tr. at 222; First Steinman Rep. at 8-10; Ahmed at 1. Although Petitioner's injury is wholly different in this case, Dr. Steinman nevertheless maintained that Ahmed supported his timeframe argument, since Fluvirin, like Pandemrix, is an H1N1 vaccine. Tr. at 246. The Ahmed study also catalogued various dates for onset of narcolepsy following flu vaccine administration, observing that it could present within up to six (or even eight) months thereafter. *Id.* In Dr. Steinman's view, Ahmed supported his contention that GBS could also present months following receipt of the flu vaccine. He later acknowledged, however, that Ahmed involved a distinguishable injury (narcolepsy) and a formulation of the flu vaccine "never used in the United States," since Pandemrix is adjuvanted (whereas U.S. versions of the flu vaccine are not). Tr. at 246.[25]

[24] On redirect, however, Dr. Steinman contradicted the above statements and suggested that he could offer an opinion regarding onset even *longer* than three months based on the concept that the relevant autoantibodies remain in the body (at detectable levels) for extended periods of time. Tr. at 361.

[25] In two other Program decisions involving narcolepsy, I have determined that Ahmed does not by itself support the contention that non-adjuvanted forms of the flu vaccine (meaning essentially *all* forms administered in the United States) can cause narcolepsy. *See, e.g., McCollum v. Sec'y of Health & Human Servs.*, No. 14-790V, 2017 WL 5386613 (Fed. Cl. Spec. Mstr. Sept. 15, 2017), *motion for review den'd*, 135 Fed. Cl. 735 (2017), *aff'd*, No. 14-790V (Fed. Cir. Feb. 25, 2019); *D'Toile v. Sec'y of Health & Human Servs.*, No. 15-085V, 2016 WL 7664475 (Fed. Cl. Spec. Mstr. Nov. 26, 2016), *mot. for review den'd*, 132 Fed. Cl. 421 (2017), *aff'd*, 726 F. App'x 809 (Fed. Cir. 2018).

With regard to onset in the present matter, Dr. Steinman proposed that Petitioner's GBS-related symptoms began just before Thanksgiving 2012 (or close-in-time to November 22, 2012). Tr. at 243. Based on the literature discussed above, he opined that an onset around Thanksgiving 2012 placed Petitioner's symptomatology course (from vaccination, to first indicator of GBS, to nadir) well within the ten-week timeframe established in Schonberger. *Id.* at 248. Dr. Steinman relied primarily on the fact witness testimony (discussed above) in formulating his opinion, given the lack of confirming contemporaneous medical record evidence.[26] He further asserted that he would allow for the possibility that her symptoms began earlier in November 2012 based on the statements offered by Petitioner's friends and family (which in the aggregate support this earlier onset). *Id.* at 254 ("I could go before, but I'll clearly say at Thanksgiving . . . .").

At hearing, Dr. Steinman admitted that the long gap between Petitioner's receipt of the flu vaccine and her hospital presentation in January 2013 was atypical for a vaccine-induced GBS injury. Tr. at 232 ("[H]ow can something linger from October 31st to January 31st[?]"). Rather, the typical GBS disease course (which is well understood to be an acute process)[27] lasts two to four weeks from onset to nadir. *Id.* at 283. This did not, however, alter his opinions concerning causation in the present matter. *Id.* at 284. Considering Petitioner's overall course, Dr. Steinman opined that Petitioner's GBS was likely subacute and/or "smoldered" for weeks (or in Petitioner's case, over two months) prior to the time it became acute enough to compel her to seek emergency treatment. *Id.* at 251 ("the destructive pathology of [GBS] is gradual . . . [n]ot everything is there when the diagnosis is first made"), 252 ("some patients have clinical features and disease course similar to GBS except for a slower progression, that is, the progression that lasts longer than four weeks"), 291 (suggesting Petitioner's symptoms were "subacute rather than subclinical"). Thus, Dr. Steinman concluded that Petitioner's symptom onset (beginning in November 2012) gradually progressed into a more severe course (and eventual diagnosis) the following January 2013. *Id.* at 252.

To support his contention that a smoldering form of GBS is medically recognized, Dr. Steinman referenced a single article. J. Wanschitz, et al., *Distinct Time Pattern of Complement Activation and Cytotoxic T Cell Response in Guillain-Barré Syndrome*, 126 Brain 2034 (2003), filed as Ex. 69 (ECF No. 64-2) ("Wanschitz"). Wanschitz examined autopsy tissues of eleven subjects (compared to four controls) who died within one day to eight weeks of GBS onset in order

[26] At hearing, Dr. Steinman assumed that Petitioner did not seek treatment for her symptoms in the intervening months (i.e., between November 2012 and January 2013) because she worked in a healthcare-centric field, and therefore disregarded the severity of the symptoms she was experiencing. Tr. at 238 ("health professionals make the worst patients").

[27] Dr. Steinman expressly acknowledged that the "textbook" definition of GBS suggests the disease is acute in nature. Tr. at 253.

to determine if various immunological and cellular markers (i.e., T cells/proteins/antigens) present in the stages of demyelinating activity worsened or prolonged disease duration. *Id.* at 2034-38. Significantly, Wanschitz defined the GBS disease course as "acute" if the patient died *within* four weeks of identified onset, or "subacute" if the patient died four to eight weeks following onset. *Id.* at 2035. Hence, Wanschitz did not measure the period from the antecedent event speculated to have *caused* the GBS and onset – precisely the issue in this case. *Id.* (Table 1). Wanschitz concluded that damaging humoral immune responses (meaning largely antibody-mediated adaptive immune responses) predominated in the "early" stages of GBS (i.e., after recognized onset), whereas cellular immune response (T-cells as part of an adaptive response) occurred later, thereby suggesting that different therapeutic approaches would be more effective depending upon the temporal status of the patient's disease. *Id.* at 2040.

Dr. Steinman proposed that Wanschitz suggested that the "destructive pathology" of GBS is gradual (given that killer T cells require a four-week incubation period prior to being detectable in the body), and thus could take a course consistent with what Petitioner experienced. Tr. at 251-52, 298-99.[28] On cross, however, Dr. Steinman acknowledged that Wanschitz focused primarily on the timeframe surrounding myelin destruction within the context of an existing case of GBS – not the overall timing or progression of GBS symptoms measured from its origin (whether due to wild infection or otherwise). *Id.* at 282.

Dr. Steinman also referenced a GBS textbook excerpt[29] in support of his contention that GBS could be subacute and/or smolder for weeks before reaching nadir. Tr. at 252 ("progression [of GBS can] last[] longer than four weeks"); *but see* Menze at 167, 179-80. In his view, Menze suggested that once a diagnosis of GBS is made, it could "progress[] for more than four weeks until it really bottoms out." *Id.* Notably, however, the text referenced by Dr. Steinman applies only to the course of GBS *following* its onset (which in this case would mean that Petitioner's nadir should have been reached by the end of December at the *latest* – a month before Petitioner sought emergency treatment). Menze at 167 ("current diagnostic criteria include <4 weeks of progression to clinical nadir"). Overall, Menze describes GBS as an "acute-onset, monophasic" disorder beginning "abruptly with relatively symmetrical onset of paresthesia and sometimes pain." *Id.*

Dr. Steinman further sought to rebut the evidence in Petitioner's medical records suggesting that she may have experienced some preexisting viral infection (or respiratory tract) close-in-time to her onset of GBS. Tr. at 224, 231-32, 356, 359-60. Based on his review of the medical record, Dr. Steinman could not identify a firm viral diagnosis associated with GBS in the

[28] Dr. Steinman also asserted, correctly, that Dr. Donofrio did not contest Wanschitz's literal findings (although Dr. Donofrio did dispute that Wanschitz supports Petitioner's claim otherwise). Tr. at 255-56, 298-99.

[29] Respondent's opining expert in this case (Dr. Donofrio) is the editor of the textbook.

antecedent period prior to onset. *Id.* at 231. A flu (A/B) viral panel completed during Petitioner's hospital stay was negative. *Id.* at 260 (citing Ex. 7 at 4-5). Petitioner's bacterial panel also revealed no concerning results. *Id.* at 287. He did agree, however, that certain "heavy hitter" viruses (i.e., Epstein Barr or CMV) were not tested for or eliminated as triggers. *Id.* at 263. Dr. Steinman otherwise asserted there was not strong (or confirming) evidence of a pre-onset URI. *Id.* at 232.

Given the above, Dr. Steinman concluded that the flu vaccine was the more likely trigger of Petitioner's GBS in the absence of evidence suggesting the presence of a firm alternative explanation. Tr. at 232, 359. On cross, he nevertheless acknowledged that in most cases of viral-induced GBS, the actual precipitating virus is *not* known, and that GBS is usually deemed idiopathic in nature. *Id.* at 260, 287 ("we really don't know what causes your [GBS] in most cases"), 291. Even so, Dr. Steinman opined that he would still be reluctant to attribute Petitioner's GBS to an antecedent viral infection even if she had *not* received a flu vaccination within the preceding months. *Id.* at 285-87. At the same time, he acknowledged that he would at least consider any pre-existing viral symptoms in combination with the overall medical record when attempting to identify the most appropriate trigger. *Id.* at 286.

Occasionally during his testimony, Dr. Steinman stepped out of his role as medical/scientific expert and into the shoes of judicial "color commentator," expressing views about the proper apportionment of legal burdens and standards applicable in the Vaccine Program, or making asides about his responsibilities as an expert based upon his understanding of the applicable legal standards. *See, e.g.*, Tr. at 217, 234, 265-66 (suggesting that he could "probably structure a theory" identifying the vaccine as a substantial factor even if another cause were identified), 285, 287-88 (suggesting the method by which he would diagnose the cause of GBS "in the real world" is different from the context of a Vaccine Program case, where he is tasked by petitioners to propose a vaccine cause).

B. *Respondent's Expert – Dr. Peter Donofrio*

Dr. Donofrio, a neurologist, was Respondent's expert. Tr. at 300-55. He filed two expert reports in support of Respondent's position. *See* Expert Report, dated Nov. 30, 2015, filed as Ex. A (ECF No. 42-1) ("Donofrio Rep."); Expert Report, dated Apr. 21, 2017, filed as Ex. F (ECF No. 65-1) ("Donofrio Supp. Rep."). In his view, the flu vaccine Petitioner received in October 2012 did not precipitate her GBS. Tr. at 306-07. Rather, Dr. Donofrio attributed her condition to a pre-existing URI (and/or a combination of a URI and asthma attack caused by a cat allergy) close-in-time to her January 2013 diagnosis. *Id.* at 323; *see* Donofrio Rep. at 6-9; Donofrio Supp. Rep. at 6-7.

Dr. Donofrio is a professor of neurology and director of the MDA and ALS clinics at the Vanderbilt University Medical Center. Tr. at 301. He received his B.S. at the University of Notre Dame, and then attended the Ohio State University School of Medicine for his M.D. *Id.* He is board certified in neurology, internal medicine, electrodiagnostic medicine, and neuromuscular disorders. CV, filed as Ex. B (ECF No. 42-2) ("Donofrio CV") at 2. Dr. Donofrio is experienced in treating peripheral neuropathies like GBS and CIDP, and is a member of organizations focusing on these kinds of neuropathic conditions. Tr. at 301-02; Donofrio Rep. at 1. Among his publications is a textbook on the specific topic of peripheral neuropathy. Donofrio CV at 21. He has also co-authored peer-reviewed papers on topics related to GBS. Tr. at 302. Dr. Donofrio testified that he diagnoses patients with various forms of peripheral neuropathy on a daily basis. *Id.* at 353. Specifically, Dr. Donofrio estimated that he treats around three GBS patients per month. *Id.* He is not an immunologist, however, and does not otherwise appear to have specific expertise in that field.

Dr. Donofrio began by discussing the classical GBS symptomatology course. He defined GBS as a subacute "inflammatory autoimmune disorder of the peripheral nervous system" affecting both the motor and sensory autonomic nerve fibers. Tr. at 303, 305. GBS can be idiopathic, but "follows a viral infection or a presumed viral infection of the upper respiratory tract or in the GI system" roughly seventy percent of the time. *Id.* at 303. Dr. Donofrio explained that a typical GBS symptomatology course evolves "fairly rapidly" (i.e., over several days) with numbness/tingling in the feet and toes, which gradually ascends the legs and eventually the arms, hands, and fingers. *Id.* at 304, 311-12. Weakness in the upper and lower extremities, pain in the lower back (or posterior thighs), areflexia (absent reflexes) and unsteady gait are also common criteria for a GBS diagnosis. *Id.* at 304-05, 311-12. In his view, generalized fatigue is not a pre-acute presenting symptom of GBS, but could be a resulting symptom following a "full-blown" course. *Id.* at 312. Ninety percent of GBS patients reach nadir of their illness between two and four weeks following onset, with a plateauing of symptoms thereafter. *Id.* at 304. After treatment, the majority of patients reach a full recovery (with only fifteen percent experiencing significant deficits). *Id.*

Based on his review of Petitioner's medical record, Dr. Donofrio agreed that hospital treaters properly diagnosed her with some form of "explosive" GBS (given her presenting symptoms documented in the contemporaneous record). Tr. at 307, 329 ("I think the preponderance of the clinical evidence and laboratory evidence pointed to [GBS] with some ocular involvement"); Donofrio Supp. Rep. at 3, 5; Donofrio Rep. at 6. Consistent with Dr. Steinman, Dr. Donofrio acknowledged that Petitioner's GBS could be classified as the Miller-Fisher variant or "Miller-Fisher-plus syndrome." Tr. at 306, 330.[30] In addition to the classic GBS symptoms, the

[30] Dr. Donofrio's first expert report suggested that Petitioner's GBS included some atypical features, including hyperreflexia and a normal EMG and nerve conduction study. Donofrio Rep. at 6. He suggested that these variants

Miller-Fisher variant typically presents with a "triad" of cranial nerve abnormalities (including eye movement weakness, areflexia in the arms and legs, and ataxia, usually of walking) *after* onset of the more typical peripheral nerve involvement. *Id.* at 306, 317; Donofrio Rep. at 5. Miller-Fisher-plus, in his view, encompasses the triad discussed above, but can also implicate other cranial nerves (for example, those responsible for proper vocal control). Tr. at 330.

However, and relying on his understanding that a classical GBS course spans a two- to four-week period, Dr. Donofrio vehemently disputed Dr. Steinman's assertion that Petitioner's GBS "lurked" for months before reaching nadir. Tr. at 316 ("[eleven] weeks would be a stretch for me to accept"), 353-55. In his view, Dr. Steinman's opinion regarding Petitioner's GBS course was inconsistent with what is known in the medical/scientific community about the disease's progression (from onset to nadir). Dr. Donofrio opined that a similar disease course occurring over a timeframe *longer* than four weeks would likely evidence an illness more along the lines of CIDP[31] or SIDP[32] – peripheral neuropathies distinguishable from that which Petitioner experienced (and diagnoses she never received). *Id.* at 306.

In challenging Petitioner's contentions that GBS could take a longer course than is commonly understood, Dr. Donofrio took direct issue with the Wanschitz post-GBS autopsy study. Tr. at 318-20. Although he did not question the reliability of its specific findings, Dr. Donofrio proposed that Wanschitz was generally unhelpful in predicting the timeframe of a GBS disease course because it did not address "pre-onset" features of GBS relevant under Petitioner's theory,

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might suggest that Petitioner was suffering from brainstem encephalitis rather than GBS. *Id.* But it appears that Dr. Donofrio conceded this point at hearing. His supplemental expert report also states an affirmed opinion that Petitioner was properly diagnosed with GBS. Donofrio Supp. Rep. at 3. But this concession did not detract from the thrust of Dr. Donofrio's opinion (considering the strong evidence suggesting Petitioner's alleged injury did not manifest in an acceptable timeframe).

[31] CIDP, or "chronic inflammatory demyelinating polyneuropathy," is defined as a "slowly progressive, autoimmune" type of polyneuropathy, characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves. *See Dorland's Illustrated Medical Dictionary* 361, 1491 (32nd ed. 2012). Although Dr. Donofrio acknowledged that GBS and CIDP can manifest similar symptoms, he maintained that CIDP should not be considered "chronic" GBS. Tr. at 348. Rather, in his view, the two are different illnesses (as evidenced by the accepted treatment protocol for each). *Id.* at 348-49. I have previously also found this to be an accurate characterization of the difference between GBS and CIDP. *See, e.g.*, *Strong v. Sec'y of Health & Human Servs.*, No. 15-1108V, 2018 WL 1125666 (Fed. Cl. Spec. Mstr. Jan. 12, 2018).

[32] Dr. Donofrio testified that SIDP (or "subacute inflammatory demyelinating polyneuropathy") is like GBS, but patients with this condition typically experience nadir around eight weeks (i.e., too long to be characterized as GBS, but too short to be CIDP). Tr. at 320-21. In Dr. Donofrio's view, the condition is rare (and not well-accepted given the more modern diagnoses), as most polyneuropathy patients tend to fall in the GBS/CIDP categories. *Id.* at 321, 347-48. It is included in textbooks for inclusivity and historical significance. *Id.* at 347. Dr. Donofrio explained that Petitioner's course was not consistent with an SIDP diagnosis (even if the alleged November 2012 onset were accepted) given its eleven-week progression. *Id.* at 321.

discussing instead the progression of the disease *following* its recognized acute onset. *Id.* at 318. Wanschitz thus did not stand for the proposition that GBS could smolder gradually for weeks prior to its acute presentation. *Id.* The article also did not set forth its subject inclusion criteria (or identify any variance in treatments received or additional diagnoses considered) – which caused Dr. Donofrio to question whether its subjects were indeed properly classified as GBS patients, or whether their deaths were even attributable to GBS (something a chart in Wanschitz suggests was not the case). *Id.* at 319-20; *see* Wanschitz at 2035 (Table I).

Dr. Donofrio spent some time at hearing discussing Petitioner's symptoms during the months prior to her ER visit and subsequent hospitalization. Petitioner's medical records revealed multiple past illnesses (for example, depression and shingles) and pre-existing symptoms (such as blurred vision, incontinence, stress, and impaired hearing), all which caused Dr. Donofrio to question if her immediate post-vaccination symptoms could really be attributed to the flu vaccine, rather than reflecting a continuation of what she previously experienced before vaccination. Tr. at 308-09; Donofrio Rep. at 6-7; Donofrio Supp. Rep. at 4.

In addition, and relying on witness testimony as well as alleged contemporaneous documentation of Petitioner's fall 2012 symptoms,[33] Dr. Donofrio questioned whether any of those symptoms had any connection to her subsequently-diagnosed GBS. Those symptoms (which included vaginal bleeding, feelings of tiredness[34]/exhaustion/cold, black/blue coloring on arms, arm/chest/neck pain, sensitivity to touch, lack of appetite, and crying episodes) did not fit with the accepted GBS clinical criteria. Tr. at 311 ("[s]o when I look at this constellation of symptoms here, I would not be thinking of [GBS]"); *see also* S. Vucic, et al., *Guillain-Barre Syndrome: An Update*, 16 J. Clin. Neuroscience 733, 734 (2009), filed as Ex. C (ECF No. 43-3) (noting that the dominant clinical feature of GBS is "generalized *muscle weakness with sensory symptoms* . . . ascending from the lower to upper limbs" which "reaches nadir at 2 weeks to 4 weeks after symptom onset") (emphasis added)). The typical, presenting clinical manifestations of GBS (i.e., ascending numbness/tingling, weakness, low back pain, and unsteady gait) were not described by Petitioner (or noted by Dr. Lara) in November or December 2012, making it unlikely that these earlier-in-time symptoms could be related to a GBS course that became fulminant only in late January 2013. Tr. at 311-12; Donofrio Rep. at 6. He otherwise noted that Dr. Lara's contemporaneous visit notes did not corroborate Petitioner's claims that she was also experiencing other symptoms at this time

[33] Dr. Donofrio specifically relied on the medical visit notes from Petitioner's OB/GYN, Dr. Lara (along with Petitioner's self-documented health agenda) given the absence of any other contemporaneous appointment notes. Tr. at 309-11; Donofrio Rep. at 6.

[34] Dr. Donofrio observed that Petitioner's pre-vaccination health records indicated she was diagnosed with sleep apnea (both obstructive and central) in the years prior. Tr. at 311. In his view, this could better explain any specifically-claimed symptoms of tiredness or sleepiness. *Id.*

(including fatigue and voice hoarseness). Tr. at 309, 312. He could locate no other primary care physician or other specialist's notes confirming the worsening of her condition around this time. Donofrio Rep. at 6.

Dr. Donofrio acknowledged that Petitioner's newly-discovered health agenda/diary (as confirmed by fact witness testimony) evidenced some concerning complaints in these earlier months that could be deemed symptoms secondarily associated with GBS (including fatigue, voice hoarseness, and arm/chest pain), but did *not* constitute presenting symptoms of the disease. He also disputed any contention by Dr. Steinman that Petitioner's general feelings of fatigue in late November or December 2012 could constitute a presenting GBS symptom. Tr. at 331 (as an "initial symptom, I've never seen it"), 352.[35] Similarly, Dr. Donofrio opined that voice hoarseness is not a presenting feature of GBS. *Id.* at 314. He agreed that a raspy voice could reflect cranial involvement in the setting of a classic GBS course (i.e., congruent with limb weakness, hyporeflexia, sensory loss, etc.), but would not be evidence of early manifestation. *Id.* The bilateral arm pain Petitioner reported would also be atypical as a presenting symptom of GBS because GBS pain more commonly affects the lower back/thighs, not the upper extremities. *Id.* at 310-11, 344.[36]

Based on the above, Dr. Donofrio concluded that Petitioner's onset of GBS likely occurred closer-in-time to her hospital presentation in late January 2013 (roughly three months post-vaccination), thus falling outside the recognized, medically appropriate timeframe for a vaccine-induced GBS injury. Tr. at 322-33, 334; Donofrio Rep. at 8; Donofrio Supp. Rep. at 3. In his view, a three-month-long gap between receipt of vaccination and onset of symptoms was simply too long to reliably support causation. Tr. at 323. For support, he referenced two papers offered by Petitioner (Langmuir and Schonberger), which suggested a five- to ten-week period would be an appropriate measurement. *Id.* at 322-23. Dr. Donofrio otherwise asserted that such a long onset runs counter to accepted immunologic principles (on which Dr. Steinman relies) as they relate to onset of neuromuscular disease. Considering the immune system will generally mount an antibody response to a foreign antigen (in Petitioner's case, the anti-GQ1B) within a seven- to ten-day timeframe after infection or other insult, it would be unlikely that a vaccine (administered three months earlier) caused the production of antibodies that could have triggered an acute response so

[35] On cross, Dr. Donofrio was questioned regarding fatigue as a presenting GBS symptom in the context of an EBV-induced GBS injury. Tr. at 332-33. He persuasively reaffirmed, however, that while fatigue could be an associated symptom (i.e., in the context of other typical GBS symptoms), it would not constitute a presenting symptom. *Id.*

[36] During his direct testimony, Dr. Donofrio pointed out that Petitioner's personal health agenda and Dr. Lara's revised visit notes from 2014 both evidenced a bullet point list of similarly worded complaints (presumably to offer some suggestion that the revised notes were not wholly Dr. Lara's own recollection of the events). Tr. at 312. Regardless of her documentation (or lack thereof), Dr. Donofrio maintained, as noted above, that many of the symptoms Petitioner allegedly complained of at this time were not related to GBS. *Id.* In any event, Dr. Lara was not qualified to opine as to such a diagnosis. *Id.*

much later. *Id.* at 346. Even assuming, hypothetically, Petitioner's symptoms started around ten/eleven weeks following administration (as Dr. Steinman proposes), Dr. Donofrio opined that such a timeframe too fell outside the more accepted period (i.e., seven to eight weeks) referenced in Langmuir. *Id.* at 323.

As noted earlier, Dr. Donofrio identified a possible alternative cause for Petitioner's GBS: a pre-onset URI. Tr. at 315, 345; Donofrio Rep. at 8. Upon reviewing Petitioner's records from her January 2013 hospitalization, Dr. Donofrio referenced documented concerns by at least two treaters of a prior upper respiratory tract infection (congruent with or exacerbated by an asthma attack)[37] in the two weeks immediately prior to presentation. *Id.* at 315 (citing Ex. 7 at 4-5). A prior infection would better align with what is known about GBS (and better explain the eventual evolution of Petitioner's symptoms). Donofrio Rep. at 8 ("[i]t is well-known that [GBS] is often preceded by an upper or lower . . . respiratory tract infection or gastroenteritis in approximately 60-70% of patients"). Dr. Donofrio could not identify what virus caused the URI, and acknowledged that viral testing had not pointed to any possible such explanation. Tr. at 315. Even so, Dr. Donofrio noted that other radiologic evidence taken during Petitioner's hospitalization was supportive of this point. *Id.* Petitioner's CT scan, for example, revealed a bronchial obstruction and associated secretions, which confirmed his suspicion. *Id.* at 315-16.

Dr. Donofrio did not spend much time at hearing addressing Petitioner's proffered medical theory. Overall, he agreed that molecular mimicry is an acceptable biologic theory to explain how an autoimmune disease process could result from a viral trigger. Donofrio Rep. at 8. He seemingly also allowed for an association between GBS and receipt of the flu vaccine based on the Schonberger swine flu study. Tr. at 325, 331 ("I certainly think that theoretically [vaccines] can [cause GBS]"), 337-38; *see also* Schonberger at 117. Dr. Donofrio's written report similarly affirms this point. Donofrio Rep. at 7.

IV. Dr. Lara Fact Dispute

Before this matter was reassigned to me, the parties engaged in some discovery relating to the accuracy of the December 2012 medical record memorializing Petitioner's visit with Dr. Lara. Although (as discussed below) the outcome of this discovery does not ultimately impact my resolution of the case, I nevertheless shall briefly summarize the procedural history relevant to Petitioner's efforts to correct alleged inaccuracies in this medical record.

On November 7, 2014 (over two years following the above-mentioned visit – but prior to this case's filing in January 2015), Dr. Lara authored a letter on Petitioner's behalf seeking to

[37] Asthma alone, in his view, could not precipitate GBS. Tr. at 345-46.

elaborate on what had been discussed at the December 2012 visit. Ex. 59 at 1-2. In it, Dr. Lara stated that in 2012 Petitioner had reported "significant loss of energy on a daily basis," voice hoarseness (unrelated to allergies), throat swelling and difficulty with swallowing, numbness of the extremities and sensitivity to cold, weakness in her wrists and arms, and "sensitivity" in her nose, mouth, and eyes. *Id*. Petitioner was also noted to be depressed and tearful. *Id*. at 1. This correction was consistent with Petitioner's allegations – but not with the contemporaneously-created record from this same visit, which suggests (except for gynecologic issues) that Petitioner's health at the time was good.

Special Master Millman, to whom this case was originally assigned, noted after a status conference that the contrast between the 2014 letter and Dr. Lara's prior record, coupled with the degree to which the letter seemed to parallel Petitioner's contentions in this case, was extremely troubling. *See* Order, dated February 17, 2016 (ECF No. 48) at 1. She also noted that there was evidence that Dr. Lara had received professional discipline, putting her credibility at risk – and that it appeared that Dr. Steinman's opinion relied on contentions about onset that were rooted in the altered description of the December 2012 visit. *Id.* at 2. Special Master Millman accordingly authorized Respondent to depose Dr. Lara in order to probe these issues.

Dr. Lara's deposition did not occur until August 23, 2016, and the transcript was filed two months later. *See* Deposition Transcript, filed on October 31, 2016 (ECF No. 58). At the deposition, Dr. Lara testified that the additional symptoms outlined in her November 2014 letter were indeed reported by Petitioner, but that she had not included them in the record, as her exam was focused on gynecological issues. *See* ECF No. 58 at 9-10, 21-22. Thus, Dr. Lara maintained that Petitioner had reported these symptoms to her in December 2012, and her November 2014 letter accurately reflected their conversation at that time. *Id.* at 25-26, 28. Dr. Lara's sworn testimony did not, however, make any reference to seeing the health notes that Petitioner testified at hearing she brought to the December 2012 appointment.

At hearing, Petitioner elaborated on the circumstances of her visit with Dr. Lara and what was discussed at that time. Petitioner explained that she requested the letter correcting the earlier medical record because she noticed that the contemporaneous record "did not describe the information . . . shared with [Dr. Lara]" during the appointment. Tr. at 42. She further stated that Dr. Lara acknowledged the contemporaneous notes did not accurately describe the additional symptoms she was experiencing at the time. *Id.* at 44 ("I recall how tired you were. You were teary, and you didn't understand what was going on."). Petitioner otherwise stated that she provided Dr. Lara with the personal health agenda noted above prior to the date Dr. Lara authored her 2014 letter (presumably in hopes it would assist her in clarifying her treatment notes), and that the revised notes were an accurate description of what Dr. Lara observed, and/or was told, during the December 2012 appointment. *Id.* at 74-76, 96-97.

V. Procedural History

Mrs. Chinea filed her Petition on January 30, 2015. Pet. at 1. The parties filed the Joint Statement of Completion on February 17, 2015. ECF No. 10. Additional medical records were filed thereafter. ECF Nos. 14-17, 22-24, 29-30, 34. Respondent then filed his Rule 4(c) report on December 1, 2015, denying that Mrs. Chinea was entitled to compensation. ECF No. 41.

Thereafter, the parties began filing expert reports. Petitioner filed an initial expert report from Dr. Steinman on August 21, 2015. ECF No. 31. Respondent filed an initial expert report from Dr. Donofrio on December 1, 2015. ECF No. 42. Following a request by the Court to supplement the record with additional expert support, Petitioner filed a second expert report from Dr. Steinman on February 16, 2017. ECF No. 64. Thereafter, Respondent filed a supplemental report from Dr. Donofrio on April 24, 2017. ECF No. 65. Given the issues identified in the expert reports (and supporting fact witness declarations), the matter was set for hearing on August 6-7, 2018, in Woodland Hills, California, to determine entitlement. ECF No. 67. The matter was subsequently reassigned to me.

The hearing took place as scheduled, and included testimony from the experts identified above (along with testimony from Petitioner and multiple fact witnesses). Following the hearing's conclusion, the parties submitted post-hearing briefs on October 31, 2018. ECF Nos. 88-87. The matter is ripe for adjudication.

VI. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – *i.e.*, an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[38] In this case, Petitioner does not assert a Table claim.

[38] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of*

Health & Human Servs., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).[39]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

[39] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record

what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms.").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v.*

Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial for a (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs*., 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too

great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 91997)); *see also Isaac v. Sec'y of Health & Human Servs*., No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case – just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to – and likely undermines – the conclusion that it was not considered").

ANALYSIS

I. Overview of GBS and Relevant Program Law

As literature filed in this case establishes, GBS is a peripheral neuropathy involving rapidly-progressive and ascending motor neuron paralysis. Vucic at 733; Menze at 167. Its etiology is unknown, although two-thirds of GBS cases follow an antecedent infection (typically an upper respiratory tract or gastrointestinal infection) beginning a few weeks prior to symptoms onset. Vucic at 733 (six weeks pre-onset); Menze at 167 (two weeks pre-onset). GBS has also been reported following surgery, head trauma, and vaccination. *Id.* at 734. It is believed to have an autoimmune mechanism. Vucic at 733; Menze at 167, 180. A GBS diagnosis centers on a thorough medical assessment involving clinical presentation, nerve conduction studies, and CSF analysis. Vucic at 734; Menze at 168.

GBS's primary clinical features are generalized muscle weakness combined with sensory symptoms. Vucic at 734. GBS typically begins abruptly with paresthesia in the feet, progressing to a flaccid paralysis of the lower limbs and ascending to the trunk, upper limbs, and face (although some cases involve paresthesia in all four limbs simultaneously or paresthesia beginning in the upper limbs and descending downward). Vucic at 733-34; Menze at 167. Weakness of the facial muscles is common and is frequently bilateral. Vucic at 734; Menze at 167. Respiratory weakness is a common feature (requiring arterial ventilation in severe cases). Vucic at 734. Eighty to ninety percent of patients become nonambulatory due to weakness. Menze at 167. Other characteristics include low-grade fever, bulbar palsy, absent tendon reflexes, and increased protein levels in the cerebral spinal fluid without a corresponding increase in cells. Vucic at 733-34. The Miller-Fisher variant (consistent with Petitioner's diagnosis) is clinically characterized as evidencing additional adverse symptoms, including ophthalmological abnormalities, ataxia, and areflexia. *Id.* at 734; Menze at 168-69.

GBS patients typically reach nadir of their illness between two and four weeks following onset, with a plateauing of symptoms thereafter. Vucic at 734, 737; Menze at 167. The current diagnostic criteria include up to 4 weeks of progression to clinical nadir. Menze at 167. Although GBS is considered a monophasic illness, between seven and sixteen percent of patients suffer recurrent episodes of worsening *after* initial onset and improvement. Vucic at 734. Sequela of GBS can include severe fatigue and persistent pain in some cases. Menze at 179. The majority of patients reach a full recovery (with only ten to twenty percent experiencing significant deficits). Vucic at 737. Up to one-third of GBS patients require some alteration to their daily routine due to the residual functional deficits. *Id.* Adverse prognosis factors can include: older age at disease onset (i.e., >50 years), severity of the disease course at nadir, rapid onset, and the presence of an underlying infection. *Id.*

The association between the flu vaccine and GBS is well-established in the Vaccine Program. *See, e.g., Strong v. Sec'y of Health & Human Servs.*, No. 15-1108V, 2018 WL 1125666 (Fed. Cl. Spec. Mstr. Jan. 12, 2018); *Stitt v. Sec'y of Health & Human Servs.*, No. 09-653V, 2013 WL 3356791 (Fed. Cl. Spec. Mstr. May 31, 2013); *Stewart v. Sec'y of Health & Human Servs.*, No. 06-777V, 2011 WL 3241585, at *16 (Fed. Cl. Spec. Mstr. July 8, 2011); *see also Barone v. Sec'y of Health & Human Servs.*, No. 11-707V, 2014 WL 6834557 (Fed. Cl. Spec. Mstr. Nov. 12, 2014). Indeed, GBS was added in 2017 as a Table Claim for the flu vaccine (although this case does not involve such a claim). *See* 42 C.F.R. § 100.3(a). Accordingly, my resolution of Petitioner's claim does *not* turn on a finding, under *Althen* prong one, that (for purposes of adjudicating a Program claim) the flu vaccine "can cause" GBS, for that question has been thoroughly examined and answered in the affirmative.

There are nevertheless some limits to the kinds of fact patterns that successfully establish that the flu vaccine "did cause" a particular petitioner's GBS under the second *Althen* prong. In most successful non-Table cases, onset of symptoms is demonstrated to have occurred no longer than six to eight weeks after vaccination. *See, e.g.*, *Barone*, 2014 WL 6834557, at *13 (eight weeks is the longest reasonable timeframe for a flu/GBS injury). I am aware of no published Vaccine Program decisions that have found a timeframe longer than two months to be medically acceptable. *See, e.g., Aguayo v. Sec'y of Health & Human Servs.*, No. 12-563V, 2013 WL 441013, at *4 (Fed. Cl. Spec. Mstr. Jan. 15, 2013) (three and one-half month onset for flu/GBS injury deemed too attenuated to be causal); *Corder v. Sec'y of Health & Human Servs.*, No. 08-228V, 2011 WL 2469736, at *27-29 (Fed. Cl. Spec. Mstr. May 31, 2011) (proposed four-month onset period from vaccination to GBS injury is too long; two months is the longest reasonable timeframe).

Such limits are in keeping with well-recognized Program case law. It is not enough for a petitioner to argue that her illness post-dated receipt of a particular vaccine – for that is another way of simply invoking the temporal relationship between vaccine and injury, something understood in the Program to have little evidentiary bearing when determining entitlement. *See, e.g.*, *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014) ("[a] temporal correlation alone is not enough to demonstrate causation").

II. Petitioner Has Not Established That Her Symptoms Before January 2013 Were More Likely Than Not Related to Her Subsequently-Diagnosed GBS

Before determining whether Petitioner has carried her overall burden in this case, I must make a fact determination regarding the onset of Petitioner's first GBS-related symptoms. Petitioner argues for an onset beginning sometime in November 2012, while Respondent favors onset no sooner than a week to ten days before Mrs. Chinea's late-January 2013 hospitalization. *See* Pre-Hearing Brief, filed on Oct. 31, 2018 (ECF No. 88) at 4-5; Donofrio Rep at 8; Ex. 7 at 4.

It is undisputed that Petitioner did not see a healthcare professional between October 31, 2012 (the day she received the flu vaccine) and late January 2013 to obtain treatment for the symptoms associated with her alleged 2012 onset of GBS. And the record is largely devoid of persuasive evidence that she even *informed* any treaters before late January that she felt out of the ordinary. She unquestionably saw a gynecologist, Dr. Lara, in December 2012, and arguably informed her of her then-present symptoms (despite the fact that she saw Dr. Lara for an entirely different kind of treatment), although the contemporaneous record of this visit says nothing about the symptoms Petitioner and her witnesses described at hearing. Although Petitioner maintains that this record is in error, Petitioner has not successfully established why I should give the original,

contemporaneous document less weight than her subsequent (and somewhat self-serving) revisions.[40]

The testimony offered by the fact witnesses at hearing, however, was more persuasive. These witnesses recounted their personal observations of Petitioner's demonstrated fatigue and other symptoms in November and December 2012. All of Petitioner's fact witnesses appeared to be credible individuals, and I have no doubt that they made an honest effort to recall what they saw at the time. Their contentions were also not rebutted. I can therefore conclude that Petitioner *did* experience overall fatigue/malaise, *inter alia*, beginning in November 2012 and running into January 2013, and that these symptoms affected her professional and social life.

However – and in light of what is known regarding the typical GBS clinical presentation – I do not find that Petitioner successfully established that *any* such symptoms represented the onset of her subsequently-diagnosed GBS. Respondent and his expert, Dr. Donofrio, persuasively established that GBS is understood to be an acute-onset, monophasic disease. *See, e.g.*, Vucic at 733-34; Menze at 167. Although some of the symptoms Petitioner experienced in the fall of 2012 could be *secondarily* associated with GBS, they would not be *presenting* symptoms of the illness. Petitioner's witnesses most credibly suggested they observed Petitioner in the weeks before Thanksgiving displaying malaise and fatigue – but this is not how GBS presents. The record was otherwise not supportive of the conclusion that Petitioner was experiencing nascent GBS in November or December 2012 (and no treater evidence beyond the discredited statements of Dr.

[40] As already noted, Dr. Lara's contemporaneous record from the December 2012 visit makes no mention of any non-gynecologic complaints. The updated "version" from November 2014, by Dr. Lara's admission, was *not* solely the product of her own recollection, but was prompted by Petitioner (who sought revisions to the original document right before filing this case). *See* Deposition Transcript (filed as ECF No. 58) at 18-21. Moreover, at hearing, Petitioner revealed that she had located a previously-undisclosed set of notes that she purported to always prepare when attending a visit with a medical provider, and which she claimed to have brought to Dr. Lara in December 2012 – and yet no mention of these notes was made at all during Dr. Lara's deposition. Dr. Lara's own credibility was also properly called into question during this case, given her prior professional misconduct. *See, e.g., Swick v. Sec'y of Health & Human Servs.*, No. 13-526V, 2018 WL 1514453, at *6-7 (Fed. Cl. Spec. Mstr. Feb. 26, 2018) ("failure to disclose [a] reprimand diminishes [expert's] credibility") (citing *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 238 (2015), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017)). And although Dr. Lara did provide sworn testimony at her deposition that (to the extent it was not rebutted) should be given some consideration, her absence as a witness in this case is a further reason to give that deposition testimony less weight, because her statements have a hearsay quality, and she has not otherwise been demonstrated to have been unable to attend the hearing. *See, e.g., Pickney v. United States*, 82 Fed. Cl. 627, 636 n.8 (2008) ("[t]estimony given in a deposition may be presented to the court *if* the declarant is unavailable") (emphasis added) (referencing Fed. R. Evid. 804); RCFC 32(a).

For all these reasons, I do not find that the revised version of Dr. Lara's medical record should be given more weight than the original 2012 record. *See, e.g., Cucuras*, 993 F.2d at 1528; *Murphy*, 23 Cl. Ct. at 733 (citing *United States v. Gypsum Co.*, 333 U.S. 364, 396 (1974)). However, even if I had found the contrary, the corrected version of the December 2012 record that Petitioner favors would not alter my determination herein – for, as discussed below, I do not find that *any* of Petitioner's purported symptoms from the fall of 2012 constituted onset of her subsequently-diagnosed GBS, or were even related.

Lara exist that could be invoked for the contrary), or that any of these earlier symptoms had anything at all to do with Petitioner's late-January 2013 symptoms.

Dr. Steinman endeavored to describe a smoldering form of GBS that could not only begin with secondary symptoms but thereafter progressively meander, only becoming acute over an eleven-week period, and long after the autoantibodies he deemed essential to the condition would have first been produced in reaction to the flu vaccine. But he was wholly unsuccessful and unpersuasive in his efforts. The form of GBS he described is not recognized in the medical literature filed in this case.[41] Literature like Wanschitz discussed purportedly longer timeframes for GBS only *after* a presentation sufficiently acute for a diagnosis, and was thus unhelpful in establishing GBS's course measured from the time of initial proposed insult (in this case, vaccination). Dr. Steinman otherwise, and despite his immense credentials as an immunologist, does not have a current, demonstrated expertise in *studying* or *treating* GBS sufficient to breathe life into his theory. Instead, the theory he espoused seems the product of his admitted goal: to "provide" a theory that would be useful to the Petitioner.

Such asides at hearing also greatly undercut Dr. Steinman's overall credibility as a testifying expert. Although his familiarity with Vaccine Act claims (as a result of his frequent participation as an expert in Program cases) may have provided him some layman's insight into the relevant law, it is wholly inappropriate for a scientific or medical expert to comment *at hearing* on such legal subjects. He was not offered as an expert on Vaccine Act law – and even if he were, it is the sole purview of the judicial officer presiding over a legal case (here, the special master) to interpret and apply the law, subject to argument by counsel (and any subsequent appellate input). *See, e.g., El–Shifa Pharm. Indus. Co. v. United States,* 378 F.3d 1346, 1361 (Fed. Cir. 2004) ("it is emphatically the province and duty of the judicial department to say what the law is"). I would never permit a Program petitioner to offer a "legal expert" to comment on the proper application of *Althen* or any other controlling precedent in the Vaccine Program. Dr. Steinman's unsolicited views on such matters were thus especially unwelcome and unhelpful.[42]

All in all, the record and witness testimony does not support the conclusion that any of Petitioner's fall 2012 symptoms were GBS-related, or that she experienced any GBS-related onset before late January 2013. I therefore find that her onset occurred no sooner than January 20-28, 2013 (or within eleven days prior to her hospital presentation). *See* Ex. 7 at 4, 7-8.

[41] To the extent this proposed GBS variant resembles CIPD, I note that Petitioner was *never* diagnosed with CIDP, and Petitioner does not otherwise allege that her GBS diagnosis was inaccurate.

[42] I have criticized Dr. Steinman in other cases for testifying in this manner. *See, e.g.*, *Rolshoven v. Sec'y of Health & Human Servs.*, No. 14-439V, 2018 WL 1124737 (Fed. Cl. Spec. Mstr. Jan. 11, 2018). If Dr. Steinman continues in the future to comment on Vaccine Program legal standards in cases before me, he will see a reduction in expert fees awarded, due to the wholly unhelpful and irrelevant nature of such testimony.

III. Petitioner's GBS Onset was Too Long After Her Receipt of the Flu Vaccine to Satisfy the Third *Althen* Prong[43]

The most reliable medical literature offered in this case establishes that a reasonable timeframe for onset of GBS after vaccine administration is no more than six to eight weeks. *See, e.g.*, Langmuir at 841; Schonberger at 105. This is echoed by the timeframe set for the Table version of the claim (*see* 42 C.F.R. § 100.3 (2017)), which is grounded in scientific observation of *how* the flu vaccine would result in harmful demyelination. Langmuir/Schonberger are both routinely relied on by opining experts in the Program, as well as other special masters. *See, e.g.*, *Corder*, 2011 WL 2469736, at *27-29. And both experts in this case tended to agree that the above-mentioned timeframes are medically acceptable in the context of a flu/GBS injury. Accordingly, and measuring from the October 31, 2012 vaccination, Petitioner's GBS (if vaccine-caused) should have at least manifested by no later than the end of December 2012 – not almost a month thereafter.

Petitioner argues for a longer timeframe, but her contentions lack reliable support in science or fact. Beyond Dr. Steinman's say so, nothing was filed in this case that would credibly establish the reliability of a three month post-vaccination timeframe. Ahmed involves a different, central nervous system condition (narcolepsy) with a wholly different pathogenic mechanism, and therefore the length of time it might take for an H1N1 flu vaccine to trigger that condition cannot be applied credibly to an entirely different injury. Wanschitz does not address the question presented herein – the expected timeframe from *insult* (in this case, vaccination) to onset – and therefore the individual reliability of its specific findings cannot be expanded to mean that the timeframe for GBS is potentially much longer than existing science suggests. Dr. Steinman's testimony on the topic also acknowledged that Wanschitz researchers were primarily focused on measuring myelin destruction following acute onset (not the pre-acute stage). *See* Tr. at 282. And Dr. Steinman's own experience in treating GBS (which would presumably inform him of clinical

[43] As already noted, I do not include an extended discussion of the first *Althen* prong (which Petitioner effectively satisfied). I also do not engage in an extended *Althen* prong two analysis, given my determination that the timeframe for onset of Petitioner's GBS was too remote from vaccination to be deemed medically reasonable. *See, e.g.*, *Hunt v. Sec'y of Health & Human Servs.*, 123 Fed. Cl. 509, 524-25 (2015) (citing *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 355-56, *aff'd*, 475 F. App'x 765 (Fed. Cir. 2012)). However, I note that the record does not support the conclusion in this case that the flu vaccine "did cause" Petitioner's GBS. Her symptoms did not reflect an ongoing inflammatory process (sufficient to corroborate her contention that she was experiencing some kind of autoimmune process), or the manner in which GBS most commonly would progress, and the medical record does not establish that any contemporaneous treaters (not prompted by Petitioner's views about a causal association) separately opined that the October flu vaccine likely caused her January illness. The fact that she tested positive for the anti-GQ1B antibody (which is unquestionably associated with the Miller-Fisher GBS variant with which she was diagnoses) also does not help Petitioner, even if the flu vaccine can be associated with that antibody. Dr. Steinman did not persuasively establish that a vaccine can create an antibody that thereupon takes months to instigate an acute illness like GBS, nor did he demonstrate that the antibody would cause the kinds of secondary symptoms Mrs. Chinea alleges to have experienced in November and December 2012 *before* her GBS became acute.

symptom presentation and common disease courses) was outmatched by Dr. Donofrio's demonstrated, treatment-derived understanding of the condition. Dr. Steinman's personal vouching for his timeframe theory did not imbue it with a strength it otherwise lacked.

The proposed timeframe is also deficient factually. As already noted, Petitioner's fatigue and other nonspecific symptoms in the fall of 2012 were inconsistent with how GBS is understood to manifest, and at best reflect symptoms that would follow – not precede – initial acute presentation. Although the witnesses who testified may have credibly established that Petitioner experienced these symptoms, none had any neurologic expertise, and therefore their observations of Petitioner's condition do not convert these symptoms into GBS onset. Mrs. Chinea's medical history from the October 31, 2012 vaccination to her January 31, 2013 ER visit does *not* describe a GBS course (and indeed, the contemporaneous records from when she presented to the hospital indicate that she seemed largely healthy until the week or so before – inconsistent with a vaccine-caused injury where that vaccine was administered eleven or more weeks prior).

At bottom, Petitioner has attempted to deem the actual chronology of her health history as a medically acceptable timeframe. That history was characterized by long periods of mild symptoms (never deemed significant enough by Petitioner to warrant a treatment visit) not directly associated with GBS, and which occurred prior to the time she experienced sufficiently acute symptoms to seek emergency treatment. *See, e.g.*, Tr. at 232, 251-52, 283-84, 289-90. Ultimately, Petitioner relies too heavily on the (long) temporal relationship between her vaccination and her subsequent onset of GBS, a position clearly rejected by relevant case law. *See, e.g., U.S. Steel Group v. United States*, 96 F.3d 1352, 1358 (Fed. Cir. 1996) ("[b]ut to claim that the temporal link between these events proves that they are causally related is simply to repeat the ancient fallacy: post hoc ergo propter hoc"); *Fricano v. United States*, 22 Cl. Ct. 76, 80 (1991) ("[P]ost hoc ergo propter hoc . . . is regarded as neither good logic nor good law"); *Doe/34 v. Sec'y of Health & Human Servs.*, 2009 WL 1955140, at *10 (Fed. Cl. Spec. Mstr. Mar. 4, 2009); *Pafford v. Sec'y of Health and Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *9 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). Petitioner has not successfully demonstrated that a flu vaccine administered eleven to twelve weeks before she experienced true clinical indicia of GBS could be related to, or causal of, that disease.

CONCLUSION

The evidentiary record does not support Petitioner's contention that the flu vaccine she received in October 2012 caused her GBS in the timeframe proffered, or that the symptoms she experienced in November and December 2012 were manifestations of that GBS. Petitioner has not established entitlement to a damages award, and therefore I must **DISMISS** her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[44]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[44] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.